National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination
ACUTE CARE HOSPITALS

I. Introduction

While the majority of the burden of healthcare-associated infections (HAIs) is currently associated with care provided in acute care hospitals, the movement of patients between homes, community based-settings, outpatient facilities, long-term care facilities, acute care hospitals, and other facility types occurs frequently and continuously. Thus, infection control and HAI prevention and elimination can no longer be compartmentalized within the time span from a patient's date of admission to date of discharge at any one particular facility.

The following chapters are framed as research, information systems and technology, incentives and oversight, and outreach and messaging strategies to reduce HAIs in acute care hospitals. However, the strategies are broadly applicable to multiple types of facilities and can also present a wide-ranging approach to prevent HAIs across the continuum of settings where healthcare is delivered.

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CHAPTER 1. RESEARCH

I. Introduction

A broad, comprehensive research agenda to support the national effort to prevent healthcare-associated infections (HAIs) needs to address the issue from a number of perspectives. In this chapter, four categories of scientific investigation are described which complement and build upon one another, but require the expertise and efforts of distinct investigators and the coordination of several federal agencies. The four categories are: the basic science underlying HAIs, the epidemiology of HAIs, the investigation of infection control interventions, and the implementation science for interventions to prevent HAIs.

Attention to all four of these domains of scientific inquiry is important. First, an increased understanding of the basic science underlying HAIs and their associated pathogens is critical for informing prevention efforts. A coordinated research agenda will strengthen the scientific understanding of these infections. Second, research focused on the epidemiology of HAIs needs to be strengthened and broadened. Gaps in the existing epidemiologic knowledge base should be identified, with corresponding research projects targeted to fill those gaps. Third, to build upon an expanded understanding of the basic science and epidemiology of HAIs, infection control interventions must be developed and/or refined and then evaluated. Fourth, for those practices for which the scientific evidence provides strong support, implementation research can provide an understanding of how to accelerate their widespread adoption. For example, studies should be directed to interventions that utilize technology to promote HAI prevention, such as electronic forms of clinical decision support, as well as the human and organizational factors affecting adoption of effective interventions in hospitals and other healthcare settings.

Since the publication of the 2009 Action Plan, significant investments in all four research areas have been made by the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), and the National Institutes of Health (NIH). Funding awards have been made for research to prevent HAIs, through both investigator-initiated research and grants and contracts for specific priority projects; these efforts are described in detail below. The largest investment has been for research focusing on the reduction of methicillin-resistant *Staphylococcus aureus* (MRSA). In addition, career development awards have been made to young investigators to support their HAI-related efforts.

This work has demonstrated that specific projects for understanding the basic science and epidemiology of HAIs, and enhancing the understanding of infection control interventions and their implementation, can be identified, prioritized, and executed. However, many challenges remain and new challenges continue to emerge. To assist in shaping the goals of this national initiative, this chapter will: 1) summarize progress that

has been made since the publication of the 2009 Action Plan; 2) reassess and update the identification of gaps in the existing knowledge base that inform current clinical and public health interventions to prevent HAIs; and 3) describe the approach for ongoing assessment of the coordinated federal research agenda to strengthen the science base for interventions to prevent HAIs in the U.S. healthcare system.

II. Progress Made in HAI Prevention Research, FYs 2008-2011

Four federal agencies, AHRQ, CDC, CMS, and NIH, account for the majority of federal research dollars expended to prevent HAIs. Their respective efforts are unique and reflect their agency mission and specific subject matter expertise. The section that follows summarizes the HAI research efforts of these agencies in FYs 2008-2011.

A. Funded Research

1. AHRQ

In FYs 2008-2011, AHRQ has made substantial funding commitments to support HAI research and prevention. These investments represent the significant growth of an HAI portfolio building on the Agency's longstanding focus on patient safety prevention and implementation. The AHRQ HAI portfolio was developed in collaboration with CDC, CMS, and the Office of the Assistant Secretary for Health (OASH), and funding was supplemented in several cases by CDC. A summary of AHRQ's funded HAI projects can be found at:

http://www.ahrq.gov/qual/haiflyer.htm, http://www.ahrq.gov/qual/haify09.htm, http://www.ahrq.gov/qual/haify10.htm, and http://www.ahrq.gov/qual/haify11.htm.

In brief, seven FY 2008 projects were designated to identify and help suppress the spread of MRSA and related infections. These projects used electronic and administrative data, and surveillance and implementation strategies, with the goals of reducing the burden of MRSA infections, achieving a better understanding of community-onset and community-acquired MRSA infections, and reducing the transmission of MRSA across healthcare settings.

In FY 2009, an additional 6 projects were funded. These projects addressed a broader array of HAI challenges, including MRSA, *Clostridium difficile* infection (CDI), surgical site infection measurement, HAI data challenges, and antimicrobial-resistant *Enterobacteriaceae*. In particular, in 2009 AHRQ funded an expansion of the Comprehensive Unit-based Safety Program (CUSP), which is based on an Intensive Care Unit Safety Reporting System developed by the Johns Hopkins University Quality and Safety Research Group, Baltimore, Maryland. CUSP was successfully deployed in the Keystone initiative that reduced central line-associated bloodstream infections (CLABSI) in over 100 Michigan Hospital intensive care units, or ICUs. ¹

¹ Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *New England Journal of Medicine* 2006; 26:2725-32.

This expansion reaches to all 50 States, adds hospitals in States already participating in the program, extends to other settings in addition to ICUs, and broadens the focus to other types of infections, such as catheter-associated urinary tract infections (CAUTIs).

AHRQ's FY 2010 projects built upon and significantly expanded the earlier work. These projects addressed multiple aspects of the HAI problem, ranging from optimizing pre-operative surgical prophylaxis to the use of universal glove and gowning, and from proactive risk assessment in ambulatory surgery centers to improving infection control in End-Stage Renal Disease facilities. These initiatives were coordinated with activities supported by the American Recovery and Reinvestment Act of 2009, such as those of CDC and State Departments of Health, to help achieve a coordinated impact on the HAI problem.

In FY 2011, AHRQ continued to expand on successful projects and programs funded in earlier years. Driven by the enormous success of the CUSP-CLABSI project, new programs funded in this fiscal year include: promotion of the nationwide spread of CUSP for CAUTI; development and implementation of a Surgical Unit-based Safety Program, an adaptation of CUSP for the surgical environment, to reduce surgical site infections (SSI) and other surgical complications; and development and pilot-testing of a CUSP for prevention of ventilator-associated pneumonia (VAP). Other newly funded projects include the study of interventions designed to reduce infections associated with *Clostridium difficile*, as well as MRSA and other multi-drug resistant (MDR) organisms, and novel projects related to the use of work systems factors and the built environment as means to maximize and sustain successful HAI reduction efforts. A new 36-month project will synthesize the results of AHRQ-funded HAI projects in FYs 2007-2010. The twin aims of this project are to identify and promote the application of effective HAI prevention approaches and to identify gaps in the HAI science base that can be filled with additional research.

2. CDC

CDC uses its HAI subject matter expertise to facilitate a robust portfolio of HAI prevention research. The CDC Prevention Epicenters Program is a network of academic centers with which CDC performs collaborative research on the epidemiology and prevention of HAI. The program has successfully performed research studies across a wide spectrum of topics relevant to the prevention of HAIs, including prevention of bloodstream, surgical and urinary tract infections, VAP, CDI, and MDR organisms such as MRSA. The program has produced more than 150 peer-reviewed publications on these subjects, including the research that was critical to development of novel HAI prevention strategies, such as the use of routine chlorhexidine bathing as an infection control intervention. In addition, the Prevention Epicenter investigators have performed a number of studies that resulted in novel and improved HAI surveillance strategies. A summary of the program's accomplishments can be found at http://www.cdc.gov/ncidod/dhqp/epicenter.html. In 2011, CDC formed the Safety and Healthcare Epidemiology Prevention Research

Development (SHEPheRD) program, which provides a mechanism for developing and implementing HAI prevention research on a contractual basis. The SHEPheRD Program includes 13 partners uniquely positioned for HAI prevention research, including academic experts in the field, large healthcare facility networks interested in participating in HAI prevention research, and entities with healthcare information on large patient populations that can be used to measure longitudinal outcomes of HAIs and the impact of prevention efforts. Over 2,500 hospitals and insurers covering more than 200 million lives are represented in the SHEPheRD program. CDC also utilizes its surveillance systems, including the National Healthcare Safety Network (http://www.cdc.gov/nhsn/) and the Emerging Infections Program (http://www.cdc.gov/ncpdcid/deiss/eip/), to conduct epidemiologic research that informs prevention efforts and provides estimates of national HAI burden and trends. CDC also conducts ongoing laboratory research to: 1) improve understanding of epidemiologically important pathogens, 2) confirm and characterize unusual antimicrobial resistance patterns and delineate mechanisms of resistance, and 3) develop optimal methods to decontaminate environmental surfaces and water in healthcare settings.

From FY2008 to present, CDC has utilized its extensive expertise to advise AHRQ on targeting Congressional appropriations for HAI research. During this time, CDC developed research proposals that were adopted by and funded through AHRQ research programs, provided technical support to AHRQ personnel, and in some cases, provided supplemental funding for AHRQ research projects. CDC experts continue to provide primary subject matter expertise for a number of AHRQ-funded projects.

3. CMS

CMS is working collaboratively with other federal health agencies on several HAI research initiatives. Specifically, CMS is partnering with AHRQ and CDC to develop an algorithm to identify claims-based markers of HAIs originating at surgical care settings. CMS is also working with AHRQ, CDC, and OASH to evaluate the Hospital-Acquired Conditions (HAC) program, which includes Present on Admission (POA) indicator reporting. In addition, CMS, AHRQ, and CDC are collaborating to improve HAI control in end-stage renal disease facilities.

4. NIH

NIH funds a diversity of projects directly related to HAIs and many more that are focused on studies of the key pathogens involved. A link to all of the funded projects can be found at http://projectreporter.nih.gov/reporter.cfm. Search strategies can be devised according to the specific topic of choice (e.g., biofilm, *C. difficile*; MRSA; VAP, etc.). Representative projects in 2008 addressed: biofilms with Enterococcus and Staphylococcus, animal models with *C. difficile*, rapid tests for resistance or resistance genes in healthcare-associated pathogens; rapid detection of bloodstream infection; novel antimicrobials for drug-resistant *C. difficile* enterocolitis; and

antimicrobial nanocoating. Representative projects in 2009 addressed: antimicrobial resistance and hospital epidemiology; microfluidic devices for point of care diagnostics; biofilm growth on functionalized surfaces; imaging of biofilms in urinary catheters; molecular pathogenesis of *Klebsiella* pneumonia; and random hand hygiene prompts. In 2010, representative projects addressed: developing treatment of VAP caused by MDR *Acinetobacter baumanii* or *Pseudomonas aeruginosa*; evaluation of exhaled biomarkers in mechanically-ventilated patients; development of antibacterial agents and materials; gene regulation of mobility and adherence in bacteria which cause UTIs; and determining if the risk of peripherally inserted central catheter or PICC-associated CLABSI is constant over catheter dwell time in neonates. Representative projects in 2011 addressed: development of novel inhibitors intended for treatment of *C. difficile*; characterizing biofilm infections in postsurgical, trauma, and critically ill patients; and evaluating the unintended negative effects of decolonization regiments on skin and mucosal surfaces in regards to the human microbiome.

5. Interagency Research Workgroup

In addition to these activities, the Interagency Research Workgroup directed funding towards addressing current gaps in HAI research including hand hygiene monitoring and environmental monitoring. The hand hygiene project is a technological intervention for hand hygiene monitoring and feedback through electronic tracing using wireless tracing devices placed on hand hygiene dispensers, employee badges and in patient rooms. The environmental monitoring project, in collaboration with State Health Departments, will assess the dynamics of contamination of the healthcare environment and its role in spreading MDR pathogens, in order to assess cleaning and disinfection methods to eliminate or minimize the environmental contributions to transmission of these pathogens.

Taken together, the above projects reflect a major commitment to the prevention and control of HAIs in the federal research agenda.

B. Priority Projects

In 2008, the Research Working Group of the Steering Committee for the Prevention of HAIs identified priority research projects that addressed gaps in basic science, epidemiology, infection control interventions, and implementation science for the Action Plan's identified Phase I infection types. Several of the funded projects described above were designed to address the identified priorities. A description of priority projects proposed in the 2009 Action Plan appears in Table 6. Where appropriate, the funded projects are indicated.

III. Current State of the Art and Identified Gaps in Knowledge and Practice

A. Gaps in Knowledge and Practice: Cross-cutting Issues

In preparation for identifying specific research areas, the working group identified gaps in the existing knowledge base regarding HAIs. Several cross-cutting issues emerged in each area of research:

1. Basic Science

Understanding of the Key Pathogens is Essential

There is an overarching need to facilitate basic research that will enhance our understanding of the key healthcare-associated pathogens. This knowledge will ultimately lead to better means of diagnosis, prevention and treatment.

The Acquisition of Healthcare-Associated Pathogens is Poorly Understood

The scientific basis for the acquisition (including basic pathogenesis, transmission, and colonization) of numerous healthcare-associated pathogens is poorly understood. Many current practices are based on empiric observation. More biologically plausible preventive measures may be derived from additional basic, epidemiological, and translational research.

Further Elucidation of the Role of Biofilms in HAIs is Needed

Microbial biofilms are of particular interest given their well-documented role in device-associated infections. The mechanisms whereby biofilm organisms initiate a disease process are still poorly understood. In addition, it is not known what proportion of device-associated HAIs have a biofilm link, or what role biofilms plays in the spread of MDR organisms in the healthcare setting. An enhanced understanding of biofilms in indwelling medical devices could have a significant impact on HAI rates.

2. Epidemiology

Limitations in Current Surveillance Strategies Exist

A critical component of an effective prevention program is the use of standardized process and outcome data as a means to inform those responsible for implementing the program and evaluate its impact. Unfortunately, many of the current HAI surveillance strategies are labor intensive and subject to limitations as a result of poor inter-rater reliability in applying standard definitions and variable implementation of case-finding strategies.

In addition, current case-finding strategies are largely focused on identifying infections that are manifested during an inpatient stay or as a result of specific invasive procedures. Such strategies may not capture an important and potentially large proportion of HAIs that, although the direct result of care delivered during an inpatient stay or in the ambulatory care setting, have their onset in the community.

Electronic Data for Measuring Processes and Outcomes are Underutilized

Strategies that make use of existing electronic clinical data sources for creating process and outcome measures may have a number of important potential advantages, including decreasing the burden of data collection, reducing error introduced by poor inter-rater reliability, and providing the ability to track adverse events longitudinally over the spectrum of a particular patient's healthcare delivery. More research on the use of electronic data for surveillance of HAIs is needed.

The Emergence of Antimicrobial Resistance May Require Adaptations to Current Strategies to Prevent HAIs

A recent study found that 16 percent of all HAIs are caused by multidrug antimicrobial resistant organisms, half of which is MRSA infection.² The epidemiology of emergent MDR organisms in healthcare settings must be monitored to allow for appropriate adaptations to current infection control interventions including antimicrobial prophylaxis, isolation strategies, and screening strategies. These interventions will need to be evaluated and disseminated.

The Role of Vaccines in HAI Prevention Needs to be Defined

Vaccines are a powerful way to prevent thousands of infections and deaths that occur each year for diseases such as influenza and hepatitis. Currently, there are 8 vaccines licensed in the US that target pathogens that can be acquired in healthcare settings. The appropriate use of these lifesaving interventions needs to be defined.

3. Infection Control and Prevention Interventions

Multicenter Collaborative Trials Are Needed to Establish the Efficacy of New Prevention Interventions

Multicenter, collaborative trials that are carefully designed and conducted are needed to establish the efficacy of new preventive interventions for HAIs and further enhance our understanding of the efficacy of existing interventions.

Multicenter Demonstration Projects to Establish the Preventability of HAIs Have Influenced the Adoption of Recommended Practices

²Hidron AI, Edwards JR, Patel J, et al. NHSN annual update: antimicrobial-resistant pathogens associated with HAIs: annual summary of data reported to the National Healthcare Safety Network at the Centers for Disease Control and Prevention, 2006–2007. *Infection Control Hospital Epidemiology* 2008; 11:996-1011.

Preventability is defined as the proportion of all cases of a certain HAI that can optimally be prevented through the careful and concerted implementation of current or existing recommendations and or guidance.

The degree to which many HAIs are preventable has previously been the subject of debate. However, several multi-center demonstration projects have demonstrated deep reductions in CLABSIs in ICUs. For instance, the Keystone project succeeded in reducing infection rates in over 100 Michigan ICUs by two-thirds over 3 months.³ Outcomes like this one have been achieved by collaborations of large numbers of healthcare facilities simultaneously implementing multifaceted prevention programs and standardized data collection.

These projects have answered important questions regarding the preventability of this particular infection type, and likely have directly influenced practice across the United States by setting new expectations for prevention. Additional Prevention Demonstration Projects involving other targeted infections (such as SSI, CDI and MRSA) and other targeted sites of care (non-ICU acute care, non-acute care settings) would be helpful.

4. Implementation Science

Adherence to Current Prevention Recommendations Has Been Suboptimal

Adherence to current prevention recommendations in healthcare settings has been generally suboptimal, even when knowledge of recommended practices is sufficient. Several lines of evidence suggest that merely increasing adherence to *currently recommended practices* can result in a dramatic reduction in infection rates, at least for some infection types.

Through implementation science, a better understanding of the barriers to adherence, and strategies to overcome those barriers, are needed to promote improvements such as the following:

- a. Understanding of human and organizational factors that affect adoption and implementation of effective strategies;
- b. Use of technology to improve adherence; and,
- c. Development and use of standardized methods (i.e., performance measures) that are feasible, valid, and reliable for measuring and reporting compliance with broad-based HAI prevention practices that must be practiced consistently by a large number of healthcare personnel (e.g., compliance with hand hygiene practices,

³ Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *New England Journal of Medicine* 2006; 26:2725-32.

proper device insertion technique, isolation precautions, environmental cleaning practices) in order to prevent infections.

The Interaction of the Varied Recommended Prevention Strategies is Poorly Understood

Current evidence-based guidelines from CDC recommend several hundred prevention strategies for the various HAIs. The extent to which these strategies interact to produce improved or poorer HAI outcomes is poorly understood.

For a given HAI, it is not always clear if all of the components of a given evidence-based bundle provide additional incremental improvements in outcomes to justify their inclusion in normal circumstances as opposed to outbreak conditions. For a given setting, it is unclear how aggressive prevention strategies for one HAI will positively or negatively impact rates of a second HAI. Understanding these relationships will require large, well-designed, multi-center clinical trials.

B. Issues Regarding the Specific Phase I Procedures and Organisms

The Research Working Group solicited input from subject matter experts at CDC and NIH and from several stakeholder professional societies to describe both the current state of the art and specific gaps in knowledge and practice across four areas:

- 1) Basic and or Laboratory Science
- 2) Epidemiology
- 3) Infection Control Interventions
- 4) Implementation Science

These are presented for the following HAIs:

- 1) Central Line-Associated Bloodstream Infection
- 2) Surgical Site Infection
- 3) Clostridium difficile Infection
- 4) Catheter-Associated Urinary Tract Infection
- 5) Ventilator-Associated Pneumonia
- 6) Methicillin-resistant Staphylococcus aureus Infection

The listing below is updated and significantly enlarged when compared with the 2009 Action Plan.

1. Central Line-Associated Bloodstream Infections

Current State of the Art Practice

Detailed recommendations on the prevention of CLABSIs have been developed by CDC and the Healthcare Infection Control Practices Advisory Committee

(HICPAC).⁴ Recent investigations have demonstrated that adherence to recommended catheter insertion practices are usually followed by a dramatic reduction in infection rates, suggesting that the preventable fraction of CLABSIs is large.

Efforts to implement "bundles" of catheter insertion practices have been quite popular in the intensive care setting, and although the rates of adherence are largely unknown, data from the National Healthcare Safety Network suggests that the rate of CLABSIs has been decreasing annually across all ICU types reporting data to that system. Although data suggest that the vast majority of CLABSIs occur outside the ICU, precise data about catheter use and CLABSI rates in this setting, including among non-hospitalized patient populations, is sparse.

Current Gaps in Knowledge and Practice

• Basic Science

- Understand the role of biofilms in the pathogenesis of device-associated infections; quantify the proportion of CLABSIs that are associated with biofilms; and,
- o Identify effective strategies and/or techniques for the early detection of CLABSI and for the differentiation of CLABSI from other bacteremias.

• Epidemiology

- Gain a better understanding of the epidemiology of CLABSIs occurring throughout the healthcare delivery system with a particular interest in the neonatal intensive care unit and outside the acute care setting;
- Identify improved methods for surveillance of CLABSI including electronic capture of CLABSI and capture of adverse events associated with catheters regardless of patient location; and,
- Develop an improved understanding of the strengths and weaknesses of using different denominators for CLABSI rates and simpler ways to capture denominators.

• Infection Control Interventions

- Determine the efficacy and unintended consequences (e.g. shift in pathogens causing CLABSI) of daily chlorhexidine bathing on CLABSI rates:
- Determine optimal strategies for catheter insertion such as the role of IV therapy teams;
- o Determine optimal use of antimicrobial-impregnated catheters;
- Develop strategies to limit biofilms as a means of preventing deviceassociated infections;
- Facilitate investigation into the optimal strategies for catheter maintenance which may include: type of dressing (e.g. chlorhexidine vs. standard); use of antiseptics for cleaning catheter hubs; efficacy and optimal use of antimicrobial lock solutions including unintended consequences of their

⁴ Healthcare Infection Control Practices Advisory Committee (H ICPAC) guidelines and publications available at: http://www.cdc.gov/hicpac/pubs.html

- use; optimal method of skin antisepsis for maintenance or insertion of catheters; impact of use of needleless connectors on CLABSI rates;
- Identify how to assure that catheters are promptly removed when no longer clinically necessary; and,
- o Identify optimal catheter care in non-hospitalized patients.
- Implementation Science
 - o Determine barriers to the implementation of CLABSI insertion prevention bundles; develop CLABSI prevention bundles directly relevant to catheter maintenance; determine cost-effectiveness of bundle components.

2. Surgical Site Infections

Current State of the Art Practice

Detailed recommendations on the prevention of SSIs have been developed by CDC and HICPAC and will be updated in 2011.⁵ Adherence to current recommendations on the use of perioperative antimicrobial prophylaxis has improved dramatically in hospitals in the U.S. since implementation by hospitals of national performance measures for antimicrobial prophylaxis, yet SSIs remain an important cause of morbidity and mortality.

Current Gaps in Knowledge and Practice

- Basic Science
 - Gain a better understanding of factors leading to the development of SSIs by the key microorganisms, their transmission in various settings, and optimal modes of prevention, diagnosis and therapy. Of particular interest is the role of biofilms.
- Epidemiology
 - Develop and standardize methods for SSI surveillance with a particular emphasis on post-discharge surveillance and ambulatory surgery surveillance; and,
 - o Determine post-operative risk factors for SSIs.
- Infection Control Interventions
 - Determine how methicillin-resistance among staphylococcal infections influences optimal antimicrobial prophylaxis practices (e.g., when should vancomycin be included? Should other agents be used?);
 - O Determine the effectiveness or comparative effectiveness of pre-operative prevention practices including but not limited to:
 - Pre-operative bathing with antiseptics;
 - Pre-operative screening, decolonization, and choice of antimicrobial prophylaxis in patients colonized with Staphylococcus aureus; (and determine the unintended consequences of these interventions such as antimicrobial resistance); and,

⁵ Guideline for the Prevention of Surgical Site Infection available at: http://www.cdc.gov/ncidod/dhqp/gl_surgicalsite.html

- Use of vaccines for *S. aureus*.
- Determine the effectiveness or comparative effectiveness of the following intra-operative prevention practices including but not limited to:
 - UV light;
 - Wound closure techniques (staples vs. sutures);
 - Optimal use of surgical antiseptic scrub; and,
 - Optimal use of skin prep solutions (alcoholic chlorhexidine vs. alcoholic iodine).
- Determine the effectiveness or comparative effectiveness of antimicrobial prophylaxis strategies including but not limited to: optimal dosing for obese patients, optimal dosing for device implantation, and intraoperative redosing;
- Determine the effectiveness or comparative effectiveness of additional perioperative management strategies including but not limited to:
 - Maintaining intra-and perioperative normothermia;
 - Role of supplemental oxygenation during surgery; and,
 - Parameters for optimal perioperative glucose control.
- Implementation Science
 - Determine barriers to implementation of current SSI prophylaxis guidelines.

3. Clostridium difficile Infection

Current State of the Art

CDI rates have been increasing in recent years, mostly due to transmission of a single, fluoroquinolone-resistant epidemic strain with enhanced virulence characteristics. Prevention strategies primarily focus on optimizing antimicrobial use and preventing transmission using basic infection control precautions. Since *C. difficile* spores can persist on environmental surfaces, the role of environmental cleaning is likely to be important.

Current Gaps in Knowledge and Practice

- Basic and/or Laboratory Science
 - Facilitate research to enhance our understanding of factors leading to the development of CDI, transmission in various settings, and optimal modes of prevention, diagnosis and therapy. Logical areas for attention include but are not limited to: immunity, gut ecology, toxin biology, and drug resistance.
- Epidemiology
 - Facilitate epidemiologic understanding of factors related to the development of C. difficile in acute care and community based settings including epidemiology of antimicrobial use; the role of asymptomatic carriers in disease transmission; an understanding of the incubation period between acquisition and onset of infection;

- Gain an enhanced understanding of the burden of CDI in the United States including but not limited to an understanding of the relative importance of setting of onset (particularly community onset); healthcare exposures and the different sources of healthcare exposures (environment versus healthcare workers);
- Develop methodology for measuring transmission and burden of CDI in non-acute care settings to assist with the above goals; and,
- O Determine the role of *C. difficile* in neonatal/infant diarrhea.
- Infection Control Interventions
 - Facilitate research to develop optimal approaches to environmental cleaning of healthcare settings such as the role of sporicidal agents, methods for assessing the adequacy of cleaning, and the development and assessment of the impact of a *C. difficile* environmental cleaning bundle;
 - Optimize additional CDI prevention practices to reduce transmission of *C. difficile* in healthcare facilities such as:
 - the duration of contact precautions (following symptomatic infection)
 - the incremental benefit of soap and water versus alcohol hand gel
 - determine the role of hand contamination after glove use
 - o Define optimal measures to reduce unnecessary antimicrobial use; and,
 - o Determine the role of gastric acid suppression.
- Implementation Science
 - Develop methods to measure and report compliance with personal protective equipment and environmental cleaning.

4. Catheter-Associated Urinary Tract Infection

Current State of the Art

Detailed recommendations on the prevention of UTIs have been developed by CDC and HICPAC.⁶ From 15 percent to 25 percent of hospitalized patients may receive a short-term indwelling urinary catheter; ^{7,8} for the elderly, catheter use is much higher. In many cases, catheters are placed for inappropriate indications, and healthcare providers are often unaware that their patients have catheters, leading to prolonged, unnecessary use.

CAUTIs are the most commonly reported HAI in the US. Although morbidity and mortality from CAUTI is considered to be relatively low compared to other HAIs, the high prevalence of urinary catheter use leads to a large cumulative burden of infections with resulting infectious complications and deaths. In addition, bacteriuria

⁶ Guideline for Prevention of Catheter-associated Urinary Tract Infections, 2009 available at: http://www.cdc.gov/hicpac/cauti/001_cauti.html

Warren JW. Catheter-associated urinary tract infections. International Journal of Antimicrobial Agents 2001;17:299-303.

⁸ Weinstein JW, Mazon D, Pantelick E, et al. Infection Control Hospital Epidemiology 1999; 20:543-548.

⁹ Klevens RM, Edwards JR, Richards CL, Jr, et al. Public Health Reports 2007;122:160-166.

frequently leads to unnecessary antimicrobial use, and urinary drainage systems may serve as reservoirs for MDR bacteria and a source of transmission to other patients.

Current Gaps in Knowledge and Practice

- Basic and/or Laboratory Science
 - Facilitate research to enhance our understanding of factors leading to the development of CAUTI, and optimal modes of prevention, diagnosis and therapy. A logical area for attention is biofilms; and,
 - o Identify methods to differentiate bladder colonization from CAUTI in patients with catheters.

Epidemiology

- Explore the epidemiology of CAUTI and asymptomatic bacteriuria including the incidence, outcomes, and relative contributions to antimicrobial use;
- Identify methods to improve the surveillance of CAUTI including determining the accuracy of surveillance definitions in select populations (e.g. elderly patients) and methods for electronic capture of CAUTI;
- Understand the epidemiology of antimicrobial resistance of uropathogens considering the role of different urinary catheter systems as reservoirs for resistant bacteria and the presence of resistance to antimicrobial/antiseptic coatings; and,
- Quantify unnecessary urinary catheter use and its consequences (trauma, encrustation).

• Infection Control Interventions

- O Determine the role of newer catheter materials and technology in prevention of CAUTI (including patient populations most likely to benefit):
 - Antimicrobial and antiseptic-impregnated catheters
 - Portable ultrasound in patients to reduce unnecessary catheter insertions or irrigations (in catheterized patients)
- Define appropriate catheter use in specific circumstances and the risks and benefits of alternatives strategies for bladder management (such as condom catheters in male patients). Populations of interest might include patients receiving thoracic epidural anesthesia, incontinent patients and patient with advanced stage (III or IV) pressure ulcers with incontinence or residing in nursing homes;
- o Determine role of antiseptics in preventing CAUTI (e.g., methanamine);
- o Determine optimal methods of meatal hygiene during catheterization;
- Identify engineering control strategies (e.g., spatial separation) of catheterized patients to prevent transmission of antimicrobial resistant urinary pathogens; and,
- Further the understanding of catheter management for patients requiring chronic urinary drainage (timing and appropriateness of routine catheter changes, alternatives to indwelling urethral catheter and bag drainage, methods for preventing encrustation, management of patients with leg bags, new prevention strategies such as bacterial interference, optimal

cleaning and storage procedures for clean intermittent catheterization technique).

- Implementation Science
 - o Identify approaches to limit unnecessary catheter use (both insertions and duration).

5. Ventilator-Associated Pneumonia

Current State of the Art

Detailed recommendations on the prevention of VAP have been developed by CDC and HICPAC.¹⁰ VAP is a major cause of healthcare-associated morbidity and mortality among ICU patients.

Unlike most other ICU infection syndromes that have relatively low mortality rates, the mortality rate for VAP in most studies has ranged from 20 percent to 50 percent. More recent estimates from studies using multi-state modeling suggest that the attributable mortality may be lower, around eight to ten percent. For patients in critical care units, VAP contributes disproportionately to poor outcomes and substantially higher costs of care. Current approaches to preventing VAP rely on evidence-based strategies that minimize intubation, the duration of mechanical ventilation, as well as risk of aspiration of oropharyngeal pathogens.

Multiple resistant microorganisms are playing an increasingly important role in the pathogenesis of VAP, particularly among infections occurring after the first week in the ICU. These pathogens contribute significantly to the increased costs, morbidity, and mortality associated with this syndrome.

Current Gaps in Knowledge and Practice

- Basic and/or Laboratory Science
 - Facilitate research to enhance our understanding of factors leading to the development of VAP infection, and optimal modes of prevention, diagnosis and therapy. Logical areas for attention include but are not limited to immunity, ecology, and biofilms; and,
 - Evaluate the effect of inflammatory lung injury and trauma on the susceptibility to VAP.
- Epidemiology

 Identify and gain consensus for a definitional and diagnostic approach to VAP that has adequate test characteristics, is feasible across facilities, and can be used for clinical decision-making, and similarly gain consensus on

¹⁰ Healthcare Infection Control Practices Advisory Committee (H ICPAC) guidelines and publications available at: http://www.cdc.gov/hicpac/pubs.html

¹¹ Nguile-Makao M, Zahar JR, Francais A, et. al. Attributable mortality of ventilator-associated pneumonia: respective impact of main characteristics at ICU admission and VAP onset using conditional logistic regression and multi-state models. *Intensive Care Medicine* 2010; 36:781-789.

a definitional approach useful for surveillance purposes. Specific diagnostic issues may include:

- Role of diagnostic bronchoscopy with culture
- Role and importance of various microbiological culturing techniques, including quantitative cultures
- Role of surrogates for VAP (see next bullet)
- Identify and evaluate surrogates for VAP to assess quality of care for ventilated patients that are objective, simple to gather, amenable to electronic determination, and predict patient outcomes. Measures are needed to allow interfacility comparisons and for objective evaluation of the impact of prevention measures;
- Identify the relative contributions of the large number of complex and confounding variables/risk factors that influence the development of VAP including the role of broad-spectrum antimicrobials in the development of VAP caused by multiple-resistant pathogens;
- Identify the relationship of endotracheal tube-induced bacterial sinusitis to VAP;
- Better understand the natural tension between the need for adequate nutrition and the increased risk for aspiration and VAP associated with enteral nutrition solutions; and,
- Develop better methods to determine the attributable mortality and attributable length of stay of VAP that take into account the timedependent nature of the condition.

• Infection Control Interventions

- Facilitate the determination of optimal care practices for ventilated patients including: positioning, oral care (routine practices, decontamination), secretion management, and acid suppression;
- Determine the role of novel approaches such as probiotics for the reduction of VAP;
- Determine the role of various technologies in the prevention of VAP including advances in endotracheal tube design and materials (antimicrobial impregnated), internal ventilator filters and ventilator breathing filters, and less-invasive ventilatory support to reduce the use of positive pressure ventilation via endotracheal intubation or tracheostomy (e.g., CPAP, high oxygen therapy, iron lung); and,
- o Determine the role of biomarkers (e.g. procalcitonin) for reduction of unnecessary antibiotic use in VAP.

• Implementation Science

- O Determine the impact of bundles of prevention practices on adherence to prevention practices and patient outcomes; define the ideal components of the bundle; and,
- Facilitate projects to create precise operational definitions and metrics for prevention practices as well as acceptable contraindications (e.g. head of bed elevation—how much, how long, how measured, and for whom).

6. Methicillin-Resistant Staphylococcus aureus

Current State of the Art

MRSA remains an important cause of HAIs, and is endemic in most hospitals in the U.S. In addition to increasing the total burden of *S. aureus* infection, healthcare-associated MRSA infections are associated with increased morbidity and mortality compared to infections caused by methicillin-susceptible strains. MRSA also has emerged as an important cause of infection in the community. Fifty-nine percent of all purulent skin infections evaluated in U.S. emergency departments are caused by MRSA. MRSA infections, both healthcare- and community-associated, are generally caused by a very limited number of strains, suggesting that most cases result from direct or indirect person-to-person transmission of MRSA.

It is widely held that the major reservoir for transmission in the healthcare setting is infected or colonized patients, and that patient-to-patient transmission occurs indirectly via transient carriage by healthcare personnel or through contaminated shared equipment. In 2005, there were an estimated 94,000 invasive MRSA infections in the United States. These were associated with nearly 18,000 deaths. Of these invasive infections, 86 percent were associated with healthcare delivery, and two-thirds of the HAIs had their onset outside the hospital setting. Recent data suggests that between 2005 and 2008, rates of invasive healthcare-associated MRSA infection decreased. 12

Although the optimal strategy for prevention and control of healthcare-associated MRSA has not been fully determined, it is likely that successful control requires a multifaceted approach that may vary according to individual characteristics of a healthcare facility, as outlined in the CDC guidance document "Management of Multidrug-resistant Organisms in Healthcare Facilities, 2006." Additionally, there is a growing recognition that the focus of MRSA prevention on individual healthcare facilities needs to be broadened to incorporate entire geographic regions.

Current Gaps in Knowledge and Practice

- Basic and or Laboratory Science
 - Facilitate research to enhance our understanding of factors leading to the development of MRSA infection, transmission in various settings, and optimal modes of prevention, diagnosis and therapy. Logical areas for further research include, but are not limited to: biofilms, antimicrobial resistance; ecology, pathogenesis and virulence factors, and immunity; and.
 - o Facilitate development of effective S. aureus vaccine.
- Epidemiology

¹² Kallen AJ, Mu Y, Bulens S, et al. **Health Care–Associated Invasive MRSA Infections, 2005-2008.** *The Journal of American Medicine.* 2010; 6:641-648.

¹³ Management of Multidrug-Resistant Organisms In Healthcare Settings, 2006, available at: http://www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf

- Facilitate research to obtain a better understanding of colonization and transmission dynamics of MRSA within the healthcare setting. Logical areas for attention include, but are not limited to: the patient (e.g. characteristics for acquiring MRSA carriage or serving as a reservoir of transmission, role of colonization of body sites other than the nares); the environment (fomites, etc), the healthcare worker, and the role of droplet spread;
- Facilitate work to understand the epidemiology of MRSA outside the adult ICU (such as the Neonatal Intensive Care Unit) and outside and between acute care settings (within a geographic region);
- Further the understanding of the epidemiology of MRSA in the community (both community acquired and community onset MRSA and their interaction with healthcare-associated MRSA);
- Determine the preventability of endemic MRSA colonization/infection; and; and,
- Improve the current understanding of the strengths and weaknesses of different methodologies for measuring MRSA infections (discharge data vs. active surveillance).

• Infection Control Interventions

- Facilitate an understanding of the role of various prevention strategies in reducing healthcare-associated transmission of MRSA. This should include assessments of the unintended consequences of such strategies. Logical strategies include antimicrobial stewardship, improved methods for preventing transmission, and MRSA eradication strategies;
- Determine the optimal role for active MRSA surveillance to detect asymptomatic carriage (who, what body sites, when, how many cultures).
 Facilitate determination of methods to measure transmission of MRSA within a healthcare setting; and,
- Translate accepted prevention practices to areas outside the adult ICU (such as the NICU and non-acute care settings).

• Implementation Science

- Determine and disseminate optimal approaches to MRSA prevention strategies, such as antibiotic-use controls or preoperative mupirocin decolonization for selected procedures
- o Identify most effective methods for facilitating coordinated regional prevention activities

IV. Long Term Prioritization, Coordination, and Evaluation of Research Efforts

HAIs are a major cause of preventable morbidity and mortality in the United States that together greatly exceed other causes of preventable mortality such as the human immunodeficiency virus or HIV. Nonetheless, funding for the study of HAIs is magnitudes lower than funding for HIV. Addressing the nation's long-term HAI research needs is a complex undertaking that will require a coordinated effort across the federal government and with other stakeholders. Many agencies within HHS such as AHRQ,

CDC, CMS, and NIH have funded research to address HAIs and their underlying causes. This document outlines a mechanism to coordinate these efforts.

Research on the basic science, epidemiology including risk factors, testing of infection control interventions, and implementation of evidence-based practices, and effects of payment and coverage policy should be linked, so findings from each area can inform and build upon findings in the other areas. For example, if CDC finds a potential population or setting as a risk factor for an HAI, this information could help establish potential priorities for AHRQ-funded research on prevention or implementation of evidence-based practices. Additionally, collaborations will emerge (e.g., CMS, working with AHRQ, CDC and OASH is currently evaluating the effects of the HAC program.) This coordination will reduce potential duplication and enhance the impact of each agency's work.

Specifically the following mechanism for coordination is proposed:

The Research Working Group is chartered and meets quarterly. This group should be comprised of at least two representatives from AHRQ, CDC, CMS, and NIH and representatives from other HHS Operating and Staff Divisions or federal agencies, as needed. The committee has three main objectives:

- 1) Coordinate and prioritize research efforts to reduce HAIs nationwide
- 2) Design a plan and metrics for evaluating progress within the research domain to address HAIs
- 3) Serve as a contact point to communicate to external stakeholders on this issue so HHS's efforts are coordinated and linked to a broader national coalition

To coordinate and prioritize research efforts, the Research Working Group will prepare an inventory of current HHS research projects and develop a mechanism for exchanging information about these projects to take advantage of potential synergies and reduce needless duplication.

To evaluate progress made in the research domain of the Action Plan, the Research Working Group will conduct periodic assessments of the research program and the projects it has specifically funded. The Research Working Group will set up *a priori* criteria for the evaluation and a plan for the timing of evaluations, such as annually. Metrics of accomplishment could include documented improvements in care, published articles, dissemination of findings through conferences or other means, or other research products. It is important to note that successful research may demonstrate negative results or bring up more questions as well as demonstrate effective interventions. The evaluation of the program should lead to adjustments to the program in subsequent years.

To effectively carry out these activities, the Research Working Group will meet quarterly and complete an update of the research component of the Action Plan no less often than every two years.

V. Conclusion and Vision for the Future: Research as the Foundation of a Learning Healthcare System

The large knowledge gaps that exist in HAI prevention are, in part, the result of barriers to new generation of knowledge that currently exist within U.S. healthcare. In a background paper developed and presented at an Institute of Medicine-sponsored Roundtable on Evidence Based Medicine entitled "Leadership Commitments to Improve Value in Health Care," Platt and colleagues argue that evidence generation, i.e., *learning what works and what does not*, should be established as a normal part of healthcare in the U.S. 14

The authors outline major challenges confronting the development of knowledge to support the learning healthcare system. These include: 1) limited investment for research and development towards understanding how well various strategies work in practice, or how to assure that the right preventive or therapeutic regimen is offered to individuals who need it; 2) difficulty in using much of the existing data, even when it exists in electronic form, because of fragmentation among organizations that control the data, variation in the way different organizations interpret the Health Insurance Portability and Accountability Act Privacy Rule, Institutional Review Boards' varying interpretations of regulations governing the use of these data for research, and proprietary concerns of data holders; 4) important limitations in the quality and generalizability of the existing data; and 5) lack of a full understanding of the strengths and weaknesses of the different research methods, ways in which to strengthen them, and the situations in which they are best applied. Meeting these structural challenges will require sustained interest and effort by a coalition of stakeholders within and outside the federal government.

The work of the Research Working Group can perform an important function in facilitating the process of becoming a learning healthcare system. This chapter summarizes the Research Working Group's work to identify gaps in the existing knowledge base regarding HAIs, a necessary first step in the process of developing a coordinated HAI research agenda that will ultimately lead to widespread use of evidence-based infection control and prevention practices in the spectrum of healthcare settings. To do so, it is critical to understand the basic pathophysiology of HAIs, the limitations of our current surveillance methods and the promise of using electronic data for surveillance, the most effective combinations of clinical care and technology to prevent HAIs, and the most effective and efficient methods to improve adherence to current HAI prevention recommendations.

Having identified gaps, the Research Working Group has proposed research projects to address the gaps identified in basic science, epidemiology, infection control and prevention, and implementation, and the priority infection types identified in the first and second phases of this initiative. In an iterative manner, the work from the Action Plan will address gaps in knowledge and inform the priorities going forward. This framework

¹⁴ Platt R, et al. Chapter 9: Clinical Investigators and Evaluators, Leadership Commitments to Improve Value in Healthcare: Toward Common. *National Academies Press*, 2009: 217-236.

of progression and iteration from basic science through implementation will be crucial in achieving a learning culture and will complement HHS's commitment to collaboration across the federal government and with additional stakeholders to assess current research methods, funding levels, information technology use, and researcher training and to present solutions to facilitate and accelerate knowledge generation and application. The overall goal is to support the research required to aggressively combat HAIs and protect the safety of all Americans.



Table 6. Status of Ide	entified Priority Resear	rch Projects in the 2009 HHS HAI Action Plan	
	2008 HAI Action		
	Plan Project		
Domain	Number	Description	Funded Projects
		Design and implement broad-based studies that define and clearly delineate the pathogenesis of device-	
Basic Science	a. i.	associated infection	FY 2008 NIH, FY 2009 NIH
Basic Science	a. ii.	Develop strategies for preventing and/or eliminating biofilms associated with medical devices	FY 2008 NIH, FY 2009 NIH
			FY 2008AHRQ HIT 290-04-0015; FY 2008
		Perform studies of the epidemiology of bloodstream infections that occur outside of the hospital,	AHRQ HCUP HHSA290200600009C; FY 2008
		including those related to hospitalization. These studies would include an assessment of patient	AHRQ HCUP 290-04-0005; FY 2008 AHRQ
Epidemiology	b. i.	characteristics and risk factors for bloodstream infection that could lead to new prevention strategies	DEcIDE HHSA2902006000013
		Establish preventability of CDI through a regional hospital collaborative intervention to reduce endemic	
		rates through employment of tiered evidence-based recommendations (e.g., transmission reduction and	
		risk reduction through antimicrobial stewardship), peer-to-peer learning, and standardized electronic	
Epidemiology	b.ii. 1.	collection and feedback of CDI rate data using the NHSN to assess impact	FY 2009 AHRQ Action HHSA290200600012
		Establish preventability of unnecessary antimicrobial use through a multi-center collaborative	
		intervention. These efforts could include coordinated development and implementation of clinical	FY2010 AHRQ ACTION H3;FY2010 AHRQ
		diagnosis and antimicrobial use paradigms in the treatment of CAUTI and VAP, as well as in the	ACTION H4; FY 2009 AHRQ PBRN
		prevention of SSI (i.e., surgical antimicrobial prophylaxis) with the aim of reducing overall antimicrobial	HHSA209200710015, HHSA209200710013,
Epidemiology	b. ii. 2.	use	HHSA209200710008, HHSA209200710004
		Establish preventability of SSI through a multi-center collaborative intervention to reduce rates. These	
		efforts could include coordinated development and implementation of strategies to implement existing	
		evidence-based recommendations, peer-to-peer learning, and standardized electronic collection and	
Epidemiology	b. ii. 3.	feedback of SSI rate data using the NHSN to assess impact	
		Perform a large, cluster-randomized study to assess whether ICU-wide application of an MRSA	
Infection Control		decolonization strategy is effective in reducing the transmission of HAIs and mortality compared to	
Interventions	c. i.	targeted decolonization strategy guided by active surveillance for MRSA colonization	FY 2009AHRQ DEcIDE HHSA29020050031
		Support multidisciplinary investigation of the human cultural and organizational barriers at the unit and	
		institutional level (including trustees and senior management) that inhibit the successful implementation	FY2010 AHRQ ACTION H10.; FY2010 AHRQ
Implementation	a.	of prevention measures	ACTION Mod H17
		Perform studies to develop and evaluate novel and potentially automatable strategies for measuring	
		healthcare-associated infections, transmission of epidemiologically important pathogens, and related	
Implementation	b. i.	processes of care using electronic data sources routinely captured during the course of patient care	CMS
		Evaluate and validate standardized post-discharge surveillance methodology that can be used in both	
Implementation	b. ii.	inpatient and ambulatory care settings	FY 2010 AHRQ HCUP H16
		Identify and evaluate proxy measures for VAP (i.e., acute lung injury) for inter-facility comparisons that	
Implementation	b. iii.	do not require stringent diagnostic approaches	
		Develop standardized methods (i.e., performance methods) that are feasible, valid, and reliable for	
		measuring and reporting compliance with broad-based HAI prevention practices that need to be	
		practiced consistently by a large number of healthcare personnel (e.g., hand hygiene, isolation	
Implementation	b. iv.	precautions, environmental cleaning practices)	DHHS

National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination CHAPTER 2. INFORMATION SYSTEMS AND TECHNOLOGY

I. Introduction

Continuing clinical and public health concerns about healthcare-associated infections (HAIs) are motivating the healthcare community at large to redouble its efforts to enhance and extend HAI monitoring, measurement, and prevention. Advances in information technology, harmonization of disparate data standards, incentive programs designed to promote the meaningful use of electronic health records, and capabilities to connect with and integrate multiple data types and sources all create new opportunities for the U.S. Department of Health & Human Services (HHS), Operating and Staff Divisions within HHS, and other federal departments and agencies to further develop and refine strategies that focus on improving the national capacity to monitor, measure, and prevent the occurrence of HAIs. HHS and its partners within the federal government share goals with state agencies, hospitals and other healthcare organizations, healthcare practitioners, accrediting and professional organizations, and the public to take action addressing the prevention of HAIs.

Some such common goals that leverage advances in state-of-the-art information systems and technology include:

- 1. Take full advantage of healthcare data in electronic form Continue progress toward more rapid and complete detection of HAIs by increasing capabilities to exploit current and future data sources. Path-breaking efforts have used laboratory and other healthcare data in electronic form, coupled with computer-based detection algorithms, to detect HAIs, but much additional work is needed to leverage these pioneering efforts and capitalize further on the increasing availability of electronic data from the clinical record of care. This will be possible only when laboratory results and clinical observations are expressed routinely using standard terms and when automated, intelligent systems are applied to identify HAI indicators among a constellation of clinical and laboratory findings within electronic data resources.
- 2. Build bridges between healthcare information systems used for infection control and prevention, quality improvement, and patient safety Further develop integration of HAI monitoring and measurement systems with other systems used to monitor and measure healthcare quality and patient safety. This includes assuring that HAI surveillance and other areas of quality and safety surveillance are complementary and connected in ways that streamline work effort and maximize the benefits for patient care and public health. For example, an integrated approach will permit rapid detection of patterns and trends for predetermined or ad hoc sets of demographics, thus creating the opportunity to

- formulate appropriately targeted tactics and execute early prevention and intervention techniques.
- 3. Combine forces with other agencies and organizations Enhance capacity at all geographic levels for more comprehensive and timely data as a shared resource for focusing prevention efforts and measuring their effectiveness at the local, state, and national levels in terms of progress toward reducing catheter-associated urinary tract infections (CAUTI), central line-associated bloodstream infections (CLABSI), Clostridium difficile infections (CDI), methicillin-resistant Staphylococcus aureus (MRSA) infections, surgical site infections (SSI), and ventilator-associated pneumonia (VAP).
- 4. Use information systems and technology to link healthcare records and extend HAI reporting Leverage the new impetus for electronic healthcare recordkeeping in ways that link and make available HAI data for entire episodes of care, e.g., both surgical process-of-care data recorded at the healthcare facility where the patient had his/her operation as well as SSI data recorded at another healthcare facility, such as another hospital or a physician's office, when the patient seeks care there. Spur the nationwide adoption and meaningful use of electronic health record (EHR) systems that can exchange data interoperably with other systems which will yield enormous benefits, including new capacity for episode-of-care data collection and more complete measurement and analysis of HAIs.
- 5. Apply new tools for putting HAI prevention into practice Take full advantage of new investments in clinical decision support embedded in EHR systems to provide context-sensitive HAI prevention reminders or clinical guidelines, when and where they are needed. The point-of-care availability of relevant information will help guide patient care decisions and documentation, such as decisions about contact precautions designed to prevent transmission of HAIs.

Improvements in national-level HAI data collection, analysis, and reporting are integral to what HHS and other federal agencies seek to accomplish in a broad-based, national HAI prevention effort. HHS recognizes that there are some issues with the current systems, despite notable efforts in this arena by federal agencies.

As called for in the 2009 Action Plan, HHS and its component Operating and Staff Divisions are pursuing a proactive strategy to integrate data where it originates, in addition to retrospective integration of different federal systems of reporting. This broadbased strategy goes beyond addressing data "control and fragmentation" issues in clinical care and looks ahead to meaningful use of EHR systems to streamline HAI reporting and identify and capitalize on HAI prevention opportunities in the clinical workflow.

Programs at multiple agencies continue to collect and report HAI and HAI-related data in separate systems and databases that function, in effect, as "silos" perpetuating singular and isolated paths of information used for making decisions. However, efforts are underway within HHS and more broadly across federal and state agencies to consolidate and integrate HAI information flows in ways that avoid duplication of efforts and disconnects that would otherwise result in loss of potentially important information.

Promoting the linking or sharing of HAI data across systems in a more integrated fashion offers myriad opportunities to yield important benefits for comprehensive analysis and action, provided safeguards are in place to assure that the merged data are used exclusively for authorized public health purposes and are scrupulously protected from unauthorized access. For example, combining patient-level surgical process-of-care data from one system with SSI data from another system, with appropriate protections of personally identifiable health data, could provide new insights into near-term opportunities for prevention and quality-of-care improvement.

In other situations, pursuing a longer-term strategy to achieve integration is needed to enable interoperable data exchanges between separate systems and to leverage the standards-based, electronic record keeping and data sharing that are entering the mainstream of U.S. healthcare at an accelerating pace. Achieving these longer-term strategies should provide HAI data to multiple agencies with greater efficiency, economy, timeliness, comprehensiveness, and reliability than is currently possible.

II. Maintaining the Foundation for HAI Data Integration and Interoperability

Critical elements that support HAI data integration and interoperability within HHS and across federal agencies remain:

- Increased visibility and priority given to the measurement and prevention of HAIs, so agency heads will incorporate this as a key objective and important priority into their respective strategic plans. The proposed goal is the execution of these strategies in an integrated fashion with federal and external partners.
- Careful planning and close coordination across federal agencies towards gradual
 and intentional implementation of system and process changes that utilize
 common data, information, and knowledge models. This should be done to
 support the prevention of HAIs and all quality-of-care initiatives sharing common
 strategic healthcare improvement goals.
- Close collaboration with private and other public entities that promote, manage, and implement widely adopted healthcare data and technology standards and the Interoperability Standards that have been recognized by the HHS Secretary to ensure that the business case for prevention of HAIs is included in the development and ongoing maintenance of standards, including efforts to harmonize multiple domains of data.
- Proactive participation in large-scale strategies and other federal initiatives, similar to those which have been advanced by the American Health Information Community, the Healthcare Information Technology Standards Panel, and the HHS Office of the National Coordinator for Health IT (ONC). This will help shape the development and implementation of an HAI Information Architecture that works in conjunction with the Nationwide Health Information Network

(NwHIN) and the Federal Health Information Sharing Environment (FHISE) initiatives.

To the fullest extent possible, efforts to improve HAI data integration and interoperability should be aligned with the NwHIN and FHISE initiatives.

The purpose of the NwHIN is to provide a secure, nationwide, interoperable health information infrastructure that will connect providers, consumers, and others involved in supporting health and healthcare. The NwHIN is a set of standards, services and policies that enable secure health information exchange over the Internet. A group of federal agencies, health information exchange organizations, and integrated delivery networks (formerly known as the NHIN Cooperative) has participated in the development of the network standards, services, and policies.

III. Coordination of Efforts: Interagency Working Group

Various agencies across HHS have begun and will continue to collaborate to find system integration solutions in order to obtain reliable national estimates of HAIs and a more accurate view of the overall issue. The Patient Safety Working Group (PSWG), coordinated by the Agency for Healthcare Quality and Research (AHRQ), serves as the primary forum for federal partners to identify and initiate collaborations aimed at integrating HAI monitoring and measurement systems. Further, the PSWG serves as a federal linchpin for connecting HAI-related information systems to information systems that provide reporting coverage for a broad array of patient safety incidents and healthcare-associated conditions.

Thoughtful development and successful implementation of specific interagency projects is essential to improve national-level HAI monitoring and measurement. Coordination of effort, such as the interagency collaboration spawned by the PSWG, will enhance communication and program planning within HHS and between HHS and other federal departments. This is enabling problems to be approached in a more holistic fashion rather than in its disparate parts.

Programs in existence or development within one or more agencies will be identified and leveraged under the auspices of the PSWG to aid in the overall prevention strategy. This coordinated effort is reducing duplication of work and enhancing the impact of each agency's contribution to the HAI prevention and, more broadly, patient safety and quality improvement.

The PSWG can answer the call for an Interagency Working Group to coordinate and spur collaborative HAI systems and technology activities. The PSWG is comprised of at least one representative each from AHRQ, Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), and ONC, plus representatives from other agencies as designated. The representatives have an overarching understanding of their respective agency's HAI-

related systems and databases as well as the inter-relationships between these systems. Representatives have an in-depth knowledge of gaps in HAI data. Project managers of specific systems within these agencies serve as technical consultants to the PSWG. In order to facilitate regular communication, the group meets bi-monthly.

The PSWG's scope includes specific projects that can be completed with a time horizon of one to two years. A high priority is placed on projects that combine data from existing systems or foster new alignments across systems to improve capacity at the national level to benchmark progress in reducing HAIs.

Processes have been launched for reconciling differences that would otherwise impede progress in completing high-priority projects. For example, selecting a common healthcare facility identifier across CDC and CMS systems will enable HAI data reported to a CDC surveillance system to be reused in CMS's Hospital Inpatient Quality Reporting Program. Also, HAI case criteria and data requirements developed for the CDC surveillance system have been adopted for use in AHRQ's patient safety incident reporting program.

CDC-CMS collaboration will enable HAI data submitted by acute care hospitals to CDC's National Healthcare Safety Network (NHSN) to be reported from that system to the CMS quality reporting program. In the FY 2011 Inpatient Prospective Payment System (IPPS) Final Rule, which was published in the Federal Register on August 16, 2010, CMS finalized the adoption of two new measures that must be reported by acute care hospitals to the Hospital Inpatient Quality Reporting Program. Specifically, CMS began requiring participating hospitals to report CLABSIs to the NHSN beginning with January 2011 discharges, and to report SSIs to the NHSN beginning with January 2012 discharges.

AHRQ-CDC collaboration has enabled HAI definitions and data specifications already used in NHSN to be adopted for use in the common definitions and reporting formats specified by AHRQ (AHRQ Common Formats) for use by healthcare providers in collecting and submitting standardized information regarding patient safety events to Patient Safety Organizations, which in turn will submit data to national Network of Patient Safety Databases.

IV. Work Group Goals, Tasks, and Operations

The goals and tasks envisioned for an Interagency Work Group can be incorporated into the PSWG's operations¹⁵:

Goal A: Establish and maintain definitional alignment and identify standardized data elements that are needed to measure HAIs across HHS agencies and encourage existing

¹⁵ Successful completion of Work Group goals and tasks is contingent on provision of staff and financial resources.

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federal participation with Standards Development Organizations and the Health IT Standards Committee to ensure that gaps in the available standards are addressed.

Tasks:

- 1. Develop and maintain a comprehensive inventory of existing HAI databases in HHS agencies, including information about data collection, data uses, and data validation.
- 2. Broker agreement on the terms that need to be defined and the set of data elements that needs to be specified to measure HAIs.
- 3. Document term definitions, value sets, and data elements included in HAI databases in HHS agencies, specifically those needed to measure HAIs.
- 4. Establish definitional alignment and data element standardization across HHS agencies, with special emphasis on standardizing healthcare data already available in electronic form.
- 5. Identify and analyze policy and legal issues and limitations relevant to exchanging data among agencies.

Goal B: Provide guidance to enable integration of HAI data from multiple HHS databases for the purpose of benchmarking progress in reducing HAIs.

Tasks:

- 1. Reach agreement on what data are needed to benchmark progress.
- 2. Identify HHS databases that are candidates for integration, with emphasis on the strategic opportunities.
- 3. Complete a business analysis of the integration opportunities that are identified.

Goal C: Mobilize health information systems to help reinforce appropriate patient safety recommended clinical practices.

Tasks:

- 1. Compile an inventory of health information system functional components, e.g., clinical decision support. This can be used to reinforce recommended clinical practices.
- 2. Develop a plan for HHS actions that can help move functional components into wider clinical use at an accelerated pace.

Goal D: Seek strategic opportunities to make varied federal data systems interoperable to enhance understanding of HAIs.

Tasks:

1. Seek strategic opportunities to make varied federal data systems interoperable to enhance understanding of HAIs.

2. Work with the public, key stakeholders, the Health IT Policy Council, CMS, ONC and Veterans Administration to identify opportunities to incorporate measures to reduce HAIs in meaningful use clinical quality measures. To accomplish these goals and tasks, the PSWG is guided by a shared understanding of the group's purpose, scope, authority, participants, roles and responsibilities, and stakeholders.

The PSWG's work on HAIs should coalesce around four major objectives:

- 1. Establish and use an information technology strategy
 - a. Develop an overall information technology strategy to support near-term and long-term HAI data integration, and linkages between HAI and other patient safety information systems, while safeguarding data from unauthorized access and use.
 - b. Make decisions regarding specific projects and the scope and boundaries of projects incorporated within a coordinated strategy.
 - c. Establish priorities and provide oversight for interagency system integration projects.
- 2. Communicate with stakeholders
 - a. Formulate a communication strategy to be used both within and external to HHS to ensure the highest degree of understanding of priorities.
 - b. Serve as a point of contact for communication to external stakeholders so HHS efforts are coordinated and linked to a broader national coalition.
 - c. Provide status reports and updates to the overall HHS Steering Committee and look for opportunities to inform the relevant working groups and advisory committees across HHS.
 - d. Identify and serve as a conduit to appropriate points of contact within agencies for data/database information.
- 3. Maintain accountability for the work effort
 - a. Design and refine process and outcome measures to monitor progress on achieving goals within the information technology strategy.
 - b. Assist related groups (e.g., the Interagency HAIs Research working group) with the design of a set of measures and a plan to improve the measures over time to monitor the nation's performance on reducing HAIs.
 - c. Where practicable, work toward the incorporation of HAI measures into appropriate stages for the CMS Meaningful Use Clinical Quality Measures.
- 4. Minimize reporting burden and maximize information output
 - a. Formulate a related strategy to streamline and reduce redundancy in HAI reporting from healthcare facilities and limit additional data collection to ease the reporting burden on stakeholders, specifically hospitals.
 - b. Use small pilot studies and work closely with HHS Operating and Staff Divisions such as the CMS Office of Clinical Standards and Quality to determine the effectiveness of information technology solutions for minimizing burden and maximizing output before solutions are disseminated and deployed.

- c. Leverage the availability of healthcare data in electronic form, such as microbiology results data, to automate case detection and enable electronic reporting of HAI data wherever possible.
- d. Establish consistent standards and coordinated data collection methodologies for how stakeholders should submit HAI data to various HHS systems.
- e. Develop strategies to ensure that end users (i.e., the institutions and individuals entering the data) have adequate access to information technology resources and help desk functions to support end users in a manner that simultaneously reduces their burden and improves the accuracy of data input (e.g., integrated help functions, error-reporting mechanisms, etc.). As part of these strategies, develop tools for user data entry which span a broad range of technical capabilities and work flows and take into account special needs in healthcare facilities in rural and underserved communities.

V. HAI Data and Data Inventory

In the fall of 2009, AHRQ contracted with IMPAQ International and the RAND Corporation to conduct an independent evaluation of the *HHS Action Plan to Prevent HAIs*. As part of the evaluation, the evaluation team inventoried federal HAI data systems and issued a report in June 2010 that includes its findings. The federal HAI data systems included in the inventory are AHRQ's Healthcare Cost and Utilization Project (; CDC's NHSN, Active Bacterial Core surveillance system, National Health and Nutrition Examination Survey, and National Hospital Discharge Survey; and CMS's Hospital Inpatient Quality Reporting Program, specifically the Surgical Care Improvement Project (SCIP) data reported at the Hospital Compare website, Medicaid Analytic eXtract, Medicare Patient Safety Monitoring System, Medicare Provider and Analysis Review.

The data inventory was designed to (1) profile currently available HHS data systems capable of detecting HAIs, (2) support integration and interoperability projects, (3) support analysis of strengths and weaknesses of data systems, and (4) reveal gaps in surveillance. Findings from the data inventory help clarify the extent of definitional alignment and data element standardization among the federal HAI data systems inventoried: substantial differences exist across systems. However, these systems serve a variety of analytic purposes and provide data with which to measure a diverse set of HAI and prevention practice metrics.

The analysis emphasizes fundamental differences between systems that use clinical records for HAI case finding and reporting compared with systems that use administrative records for case finding and reporting. Case criteria and data requirements developed for use with clinical data sources reflect the level of detail that is available in entire healthcare records, whereas criteria and requirements for use with administrative data sources reflect the narrower range of data available in coded summaries of clinical encounters. As a result, the analysis serves as a reminder that heterogeneity between

administrative and non-administrative data sources is likely to preclude successful integration between systems that diverge so fundamentally in the records and methods used to identify and report HAI cases. Combining HAI incidence data collected and reported by hospital infection preventionists who use clinical records with HAI incidence data collected from coded hospital discharge records would have limited value owing to fundamental differences in the two approaches to HAI monitoring.

Additional analysis is needed to understand how findings from the data inventory can be used to further develop HAI data linkage or sharing data across agencies, specifically between agency systems that use comparable data sources and methodologies for HAI case finding and reporting. What are needed are granular level comparisons of data specifications that provide operational guidance on achieving system integration and semantic interoperability of HAI data from multiple databases. The data inventory is an important first step toward mobilizing health information systems and federal aggregating systems in ways that address gaps in HAI coverage at the national, state, and local levels. The PSWG is strategically well positioned to provide additional input and coordination for next steps.

VI. Integrating Sources of Data

The PSWG provides a forum for deliberations and decisions about which near-term data integration activities are of the highest priority and the processes for accomplishing shared objectives. These decisions should be guided by the understanding of the original business purposes of the data or data groupings and the metadata information available from the data inventory and other sources of information about HAI data systems. Caution should be applied when re-purposing data while also focusing attention on filling the most important gaps in HAI data coverage.

One example of leveraging current capacity is developing a means to share data between CMS's SCIP and CDC's NHSN; specifically, surgical process-of-care data from SCIP can be combined on the facility and patient levels with SSI data from NHSN. In the current environment, fundamental differences in purpose, data requirements, and methods among some systems reduce the prospects for meaningful data linkage or sharing. The forthcoming use of NHSN to report hospital-specific, SSI data to the CMS Hospital Inpatient Quality Reporting Program will enable process and outcome data to be combined at the facility level. Additional work is needed for linkage at the patient level.

A sustained and well-coordinated effort will be needed by AHRQ, CDC, CMS, ONC and other federal agencies to continue and extend the work that has begun on systems integration. New opportunities are rapidly emerging to apply new societal investments in electronic health record systems and new capacity for clinical decision support toward HAI reporting and prevention. This work should be guided and informed by the FHISE and NwHIN and should take full advantage of the healthcare technology and data standards that are entering the mainstream of electronic clinical record keeping and reporting.

Using these standards and interoperability specifications to develop, enhance, or modify federal systems would enable data integration and should connect federal systems to the standards-based EHRs that are rapidly emerging. Thorough and ongoing use of standards-based solutions should be developed to reduce or obviate the need for abstracting clinical observations from healthcare records in order to report HAI data to federal agencies. Ideally, clinical data entries describing HAIs will automatically populate HAI reports generated from EHRs.

While this scenario of electronic HAI reporting remains visionary, HHS and other federal agencies are well positioned strategically to help catalyze and coordinate the technical advances needed to make this vision a reality.

VII. Challenges and Opportunities

The PSWG and interagency collaborations face many challenges in their concerted efforts to create a successful environment for sharing of HAI information among federal agencies.

HAI data owners from a variety of sectors (including state, local, and private) should consider investing in the development and deployment of a common reporting format, as well as the infrastructure needed to share the information nationally. All of these data owners should work within the available processes of existing workgroups, committees, and organizations, such as the HIT Standards Committee and the Health IT Policy Council. Minimizing HAI data reporting burdens on healthcare facilities is a priority, as is close collaboration with accrediting organizations and healthcare professional organizations. Duplication and other data quality issues must be minimized or eliminated when data are aggregated at the national level. Finally, aggregating data from multiple sources will require agreement on common semantics for the data.

HAI solutions must be requirements driven. By continuing to focus on the data required for specific uses and user groups, decisions about information systems and technology will guided by end results rather than tools and processes. Usage scenarios must be documented and updated to assure that specific requirements are met for HAI data. It is anticipated that informatics solutions will continue to be developed in iterative phases. The integration of data from disparate sources might initially target simple collation of data, in which reports would be retrieved from existing HAI databases "as is," and made available through a shared repository.

A subsequent aggregation phase should involve developing common definitions and formats that all HAI databases would use to generate electronic information feeds to the information sharing environment. An HAI database of the future could be built and maintained using a data model that is harmonized with clinical and administrative domains, maintaining strong linkages to HAI data of interest that are captured by various healthcare systems of origin.

An HAI database of the future should contain metadata and support a standard metadata registry, and would also support a knowledgebase used for developing training, guidance, and adjustments to public health policies with respect to prevention of infections. This future database would ideally capitalize on interoperability between federal systems that enables aggregation and reuse of data from disparate systems, each of which serves a distinct, primary function as well as a secondary purpose in which data are reported to a central system.

VIII. Conclusion

A well-organized and effective interagency working group, constituted as the PSWG and informed in its deliberations and decision-making by a systematic inventory of HAI data and databases and a common information model, can continue the fact finding and analytic work needed to refine plans and define resource requirements for integration of HAI data across existing federal systems. Highest priority should be given to near- and long-term integration projects that will yield new capacity to measure national-level progress in HAI prevention.

HHS is strategically positioned to catalyze multi-agency integration efforts and foster close collaboration with other public entities and private sector organizations that have a stake in HAI data or that have lead roles in standard-setting for healthcare data and information technology. To the fullest extent possible, efforts to enhance return on investment in federal sources of HAI data should be aligned with the NwHIN and FHISE initiatives. Integrating data from HAI database sources at multiple agencies will require sustained commitment and careful project planning and execution. Successful project outcomes can establish new programmatic collaborations across federal agencies and yield benefits for analysis and action in a broad-based, national effort to prevent HAIs.

National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination CHAPTER 3. INCENTIVES AND OVERSIGHT

I. Introduction

The U.S. Department of Health & Human Services (HHS), specifically the Centers for Medicare & Medicaid Services (CMS), has a variety of tools within its statutory and regulatory authority to support the prevention of healthcare-associated infections (HAIs). These tools can be broadly classified as regulatory oversight, financial incentives, transparency and associated incentives, or some combination of these. CMS also has a number of initiatives within each of these broad categories to combat HAIs.

This chapter discusses in detail the various ways in which these tools and initiatives were used to support the nation's efforts to prevent infections. Section 1 describes regulatory oversight activities, including conditions of participation, accreditation, and survey and certification. Section 2 discusses value-based purchasing (VBP) programs and other financial incentives that encourage healthcare providers in various care delivery settings to report and reduce HAIs. Section 3 focuses on transparency and associated incentives, like Hospital Compare. Section 4 describes initiatives implemented by CMS, the Centers for Disease Control and Prevention (CDC), State health agencies, and private organizations to prevent and reduce HAIs.

II. Regulatory Oversight

A. Introduction

The Conditions of Participation (CoPs) and the Conditions for Coverage (CfCs) are the federal health and safety requirements that hospitals and other providers and suppliers must meet to participate in the Medicare and Medicaid programs. The CoPs/CfCs are intended to ensure that high quality care is provided to all patients. Compliance with the CoPs/CfCs is determined by State Survey Agencies (SSAs) or by national Accreditation Organizations (AOs). The SSAs survey hospitals to assess compliance with the CoPs. Hospitals are deemed to have met the requirements in the CoPs if they are accredited by national AOs with accreditation programs approved by CMS. All Medicare- and Medicaid-participating hospitals are required to be in compliance with CMS's CoPswhether compliance is determined through accreditation or survey.

B. Hospital Conditions of Participation

The Medicare Hospital CoPs are the health and safety standards required for the protection of all hospital patients. Revisions to the CoPs require an extensive, and, at

times, lengthy rulemaking process by CMS that reflects the ever-evolving nature of medicine and patient care, and any revisions must leave a certain degree of latitude to allow for innovations in healthcare practice that improve the quality of care and move toward the reduction of medical errors and patient harm. These innovations in patient care, if supported by well-documented research evidence, most often lead to the issuance of guidelines and recommendations, sometimes referred to as "best practices." These guidelines and recommendations are issued by federal agencies, such as the Agency for Healthcare Research and Quality (AHRQ), CDC, and the Occupational Safety and Health Administration (OSHA) within the Department of Labor, as well as by nationally recognized organizations. Historically, these federal and private entities have been able to update and disseminate these best practices more quickly than CMS has been able to revise the Medicare health and safety standards through the regulatory rulemaking process.

The hospital Infection Control CoP (42 C.F.R. § 482.42) directly addresses the reduction of HAIs. However, rather than continually revising the infection control requirements in the CoPs to meet emerging needs, the CoPs are most effectively understood as a structural framework for hospitals. The CoP requirements for organizational roles and hospital policies should be used by health systems to integrate nationally recognized infection control standards and best practices into their individual infection control programs and to change their policies and procedures if, and when, the guidelines change.

Additionally, the CMS survey and certification interpretive guidelines for the Infection Control CoP provide a vehicle for a more specific discussion of best practices in infection control for hospitals. The current Infection Control interpretive guidelines contain references to the recommendations of organizations such as the CDC, OSHA, the Association for Professionals in Infection Control and Epidemiology, the Society for Healthcare Epidemiology of America, and the Association of Peri-Operative Registered Nurses. The guidelines specifically address special challenges to a hospital's infection control program, including multi-drug resistant organisms, communicable disease outbreaks, and bioterrorism, and directly refer to current and nationally accepted sources of information for hospitals on these challenges.

C. Accreditation

As mentioned above, accreditation by a CMS-approved national AO can substitute for a State review by a SSA. If a provider or supplier entity is accredited by an approved AO, CMS may "deem" those entities as having met the Medicare requirements. Accreditation by an AO is voluntary and is not required for Medicare participation. The option to use private accreditation for ensuring provider compliance with Medicare requirements has existed in statue since 1965. A national AO applying for approval of an accreditation program must provide CMS with reasonable assurance that the AO requires accredited healthcare facilities to meet standards that are at least as stringent as the applicable Medicare CoPs. There are currently seven national AOs that have approval for 15 separate Medicare accreditation programs for hospitals, critical access hospitals,

ambulatory surgical centers, home health agencies, and hospices. New applications are under review for other types of facilities, including psychiatric hospitals.

D. Survey and Certification

The survey and certification program is designed to ensure that providers and institutional suppliers comply with the applicable health and safety standards, i.e., Conditions of Participation for providers or Conditions for Coverage for suppliers. Currently, the CMS Survey & Certification Group oversees compliance with these Medicare health and safety standards for more than 271,000 health care facilities of different types, including hospitals, laboratories, nursing homes, home health agencies, hospices, and end stage renal disease facilities. CMS works with the SSAs and, for certain types of facilities, with approved Medicare accreditation programs of private national accreditation organizations to conduct on-site facility inspections for health care facilities that seek Medicare participation. Only certified providers, medical professionals institutional suppliers, and laboratories are eligible for Medicare payments. In the case of hospitals, Medicaid payments are available only to those hospitals that satisfy the Medicare CoPs. There are approximately 7,200 active SSA surveyors nationwide (about 6,500 full-time equivalents), with roughly 500 dedicated to hospital surveys, and there are three approved private Medicare hospital accreditation programs that are responsible for inspecting over 3,600 of the almost 4900 hospitals that participate in Medicare.

On November 21, 2007, CMS published a comprehensive update of its interpretive guidelines for the hospital infection control CoP. The November 2007 revision to the hospital interpretive guidelines for infection control was updated to reflect changing infectious and communicable disease threats as well as current and nationally recognized infection control standards of practice. When deficient practices, such as deficient infection control practices, are identified through a hospital survey by a SSA, the information is captured in a database. In Between FY 2007 and FY 2010, an infection control deficiency was cited in 1.7% - 2.3% of standard hospital surveys conducted by the SSAs, and in .9% - 1.3% of complaint surveys. The database has several deficiency identifiers or tags related to various parts of the infection control regulation. With the use of specific tag identifiers for the deficient practice(s), CMS can later analyze the findings for greater insight into problem areas. For example, CMS is able to analyze the hospital deficiency citations for infection control to specifically capture whether the hospital is compliant with having the required designated infection control officer. Typically, hospital complaints have comprised the second highest volume of complaints received by CMS among all Medicare-certified facility types. When the top allegations for complaints are examined, infection control issues are consistently in the top 12 items.

E. Recommendation and Action Plan for Regulatory Oversight

Updating Guidance The Medicare Hospital Infection Control Condition of Participation was first published over 20 years ago. Since then, infections such as the human immunodeficiency virus, severe acute respiratory syndrome, West Nile virus, avian influenza, and methicillin-resistant *Staphylococcus aureus* (MRSA) (to name but a few)

have emerged and have been quickly followed by infection control guidelines that tend to be specific to each emerging infection. Federal agencies and nationally recognized organizations have typically revised these guidelines as needed to keep pace with new developments in providing safe, quality healthcare and as a way to help hospitals continue to track, monitor, and prevent such diseases.

As new sources of infection and communicable disease present additional challenges to patient care, and as new guidelines are developed to address these challenges and become the standard of practice, Medicare infection control guidance is modified to reflect these changes. Currently, the Infection Control interpretive guidelines make direct reference to the evidence-based infection control standards of practice established through nationally recognized expert organizations, including the CDC. Through annual training, reinforcement of revisions of hospital interpretative guidelines are communicated to approximately one third of all SSA hospital surveyors each year.

Improve the quality and consistency of surveys assessing hospital infection control practices. CMS and experts have identified a number of future enhancements for regulatory oversight of hospitals as recommendations:

- Incorporate enhancements, which arise from collaborative activities with the CDC, into the surveyor training program as a means of providing surveyors with illustrative examples of best infection control practices in hospitals;
- Introduce a new infection control surveyor tool to assess the Infection Control CoP. In FY 2011, working in collaboration with the CDC, a surveyor tool was developed and placed into a pretest phase in several volunteer States. In FY 2012 all SSAs will test the tool. After modifications based on surveyor feedback and assessment of effectiveness, the use of the new tool will be required during all hospital surveys of the infection control CoP, beginning in FY 2013; and,
- Require AOs to also make assessment of infection control a priority focus, and to
 either use the new infection control surveyor tool or to develop an equivalent survey
 process that achieves the same results.

III. Value-Based Purchasing Financial Incentives

A. Introduction

CMS is applying the tools within its statutory authority to enhance the quality and efficiency of services provided to Medicare beneficiaries through value-based purchasing and related initiatives. These tools include measurement and payment incentives to encourage beneficial interventions and outcomes to improve performance. Using these resources, CMS is working to transform Medicare from a passive payer to an active purchaser of higher value healthcare services.

The Preventable Hospital-acquired Conditions Provision (HAC), including the Present on Admission (POA) Indicator Reporting, and Hospital Pay-for-Reporting are hospital-related initiatives that CMS is using to promote increased quality and efficiency of care.

CMS is studying the application of measurement and payment incentives to hospitals through various demonstration projects. CMS has presented an approach to transition from pay-for-reporting to performance-based payment in the Hospital VBP Plan Report to Congress, and has begun the Hospital VBP Program. In addition, CMS has implemented pay for reporting targeting physician and post-acute care settings. Each of these initiatives is discussed below.

B. Hospital-Acquired Conditions (HACs) and Present on Admission (POA) Indicator Reporting

Inpatient Prospective Payment System Incentives

Under Medicare's Inpatient Prospective Payment System (IPPS), hospitals are encouraged to treat patients efficiently because they receive a MS-DRG-based payment for an inpatient stay based, in part, on the patient's diagnosis and severity of illness. These prospectively determined payment amounts give hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, conditions acquired in the hospital, including infections, do not generate higher payments than the hospitals would otherwise receive for cases without these conditions. To this extent IPPS encourages hospitals to avoid complications, including infections.

However, complications acquired in the hospital can generate higher Medicare payments in two ways. First, if a hospital incurs exceptionally high costs treating a patient, the hospital stay may generate an outlier payment. Because the outlier payment methodology requires that hospitals experience large losses on outlier cases before outlier payments are made, hospitals have an incentive to prevent outliers. Second, under the MS-DRGs classification that took effect for hospital payment in FY 2008, certain conditions can generate higher payments. There are currently 259 sets of MS-DRGs that further divide into two or three subgroups based on the presence or absence of a complicating condition (CC) or major complicating condition (MCC). The presence of a CC or MCC generally results in higher payment. 16

The HAC provision is one statutory provision that CMS is using to combat certain healthcare-associated complications, including infections, in the hospital setting. The Medicare statute requires CMS and the Secretary of Health and Human Services in consultation with CDC to select at least two conditions that will no longer trigger higher payment when they are acquired during hospitalization. The selected conditions must be: (1) high cost, high volume, or both; (2) assigned to a higher paying MS-DRG when present as a secondary diagnosis; and (3) could reasonably have been prevented through the application of evidence-based guidelines.

 $(\underline{http://www.federalregister.gov/articles/2010/08/16/2010-19092/medicare-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-prospective-payment-systems-program-hospital-inpatient-program-hospital-in-program-hospital-in-program-hospital-in-program-hospital-in-program-hospital-in-program-hospital-in-program-hospital-in-prog$

for-acute-care-hospitals-and-the).

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¹⁶ For a detailed discussion of the Inpatient Prospective Payment System Final Rule, please refer to the Fiscal Year 2011 Hospital Inpatient Prospective Payment Rule in the Federal Register, August 16, 2010, pp. 50081, 50092-50094

To identify whether a condition would have been present on admission and thus potentially result in a payment adjustment for a specific claim, CMS required hospitals to submit a "present on admission" indicator on claims to determine whether diagnoses were present on admission or acquired during hospitalization. On October 1, 2007, CMS began requiring hospitals to submit this information on Medicare claims. The POA indicator is necessary to identify which conditions are acquired during the hospital stay for payment purposes, and this information is also potentially valuable for the broader public health uses of Medicare data.

Beginning October 1, 2008, Medicare can no longer assign an inpatient hospital discharge to a higher paying MS-DRG if a selected condition is listed on the claim, was not present on admission, and is the only reason why a discharge would be assigned to the higher paying MS-DRG. That is, the case will be paid as though the condition were not present. Medicare will continue to assign a discharge to a higher paying Medicare-severity diagnosis-related group if the selected condition is present on admission.

The following table demonstrates how payments are made depending on the Medicareseverity diagnosis-related group assignment and the present on admission status of a single secondary diagnosis under the hospital-acquired conditions policy.

Table 7. Payments based on Medicare-severity diagnosis-related group assignment and Present on Admission Status

Medicare-severity diagnosis-related group Assignment (Examples for a single secondary diagnosis)	Present on admission Status of Secondary Diagnosis	Average Payment
Principal Diagnosis: Medicare-severity		\$5,347.98
diagnosis-related group 066		
■ Stroke without CC/MCC		
Principal Diagnosis: Medicare-severity	\mathbf{Y}	\$6,177.43
diagnosis-related group 065		
Stroke with CC Example Secondary		
Diagnosis:		
Injury due to a fall (code 836.4 (CC))		
Principal Diagnosis: Medicare-severity	N	\$5,347.98
diagnosis-related group 066		
■ Stroke with CC Example Secondary		
Diagnosis:		
■ Injury due to a fall (code 836.4 (CC))		
Principal Diagnosis: Medicare-severity	Y	\$8,030.28
diagnosis-related group 064		
■ Stroke with MCC Example Secondary		
Diagnosis:		

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■ Stage III pressure ulcer (code 707.23		
(MCC))		
Principal Diagnosis: Medicare-severity	N	\$5,347.98
diagnosis-related group 066		
■ Stroke with MCC Example Secondary		
Diagnosis:		
■ Stage III pressure ulcer (code 707.23		
(MCC))		

CC: complicating condition; MCC: major complicating condition

This table illustrates the different MS-DRG payments that result when selected HACs are present on the claim. These scenarios are for a single secondary diagnosis only, which is atypical for a hospitalized Medicare beneficiary. The presence of at least one non-HAC CC/MCC on the claim will continue to trigger the higher paying Medicare-severity diagnosis-related group.

Collaboration and Public Input in Hospital-acquired Condition Selection

CMS clinical quality experts have worked closely with public health and infectious disease experts from the CDC to identify candidate preventable HACs, review comments, and select HACs. CMS and CDC staff also collaborated on the process for hospitals to submit a POA indicator for each diagnosis listed on inpatient Medicare claims and on defining the payment implications of the various POA reporting options.

On December 17, 2007, CMS and CDC hosted a jointly-sponsored HAC and POA Listening Session to seek individual input from the over 500 organizations and individuals who participated. CMS and CDC received verbal comments during the listening session and subsequently received numerous written comments. CMS and CDC jointly sponsored a second POA Listening Session in December 2008. CMS has also sought public comment during FY 2007, FY 2008, FY 2009, FY 2010, FY 2011, and FY 2012 IPPS rulemaking. CMS noted that it will be considering additional HAC candidates, including additional infectious conditions, in future rulemaking. CMS expects to continue its collaboration with the CDC, other federal health agencies, and stakeholders in the refinement and expansion of the payment provision.

Hospital-Acquired Condition Selection Criteria

In selecting proposed candidate conditions and finalizing conditions as Hospital-Acquired Conditions, CMS and CDC staff evaluated each condition against the statutory criteria. These criteria limit which conditions can be selected for the HAC payment provision. The first criterion requires that a selected condition is high cost, high volume, or both. The second criterion requires that a selected condition trigger a higher Medicare payment. To do so, a condition must be represented by an ICD-9-CM diagnosis code that clearly identifies that condition, is designated as a complicating condition or a major complicating condition, and results in the assignment of the case to a higher paying MS-DRG when the code is reported as a secondary diagnosis. That is, a selected condition

must be a complicating condition or major complicating condition diagnosis code that would, in the absence of the HAC payment provision, result in the assignment of the case a higher paying MS-DRG.

The third criterion requires that a selected condition must be considered reasonably preventable through the application of evidence-based guidelines. Guidelines developed by entities such as the HHS Secretary's Healthcare Infection Control Practices Advisory Committee (HICPAC), professional organizations, and academic institutions were reviewed to evaluate whether guidelines are available that hospitals should follow to prevent conditions from occurring in hospitals. The absence of prevention guidelines for many potential candidate conditions, including certain infectious conditions, limits the universe of candidate conditions.

Selected Hospital-Acquired Conditions for 2012

Each year since FY 2007, after evaluating proposed candidate conditions against the statutory criteria and considering public comments received during IPPS rulemaking, CMS has finalized categories of conditions to which the HAC payment provision applies. There are currently 10 categories of HACs:

Hospital-acquired Conditions - Ten Categories of Conditions

- 1. Foreign Object Retained After Surgery
- 2. Air Embolism
- 3. Blood Incompatibility
- 4. Pressure Ulcer Stages III & IV
- 5. Falls and Trauma:
 - Fracture
 - Dislocation
 - Intracranial Injury
 - Crushing Injury
 - Burn
 - Other injuries
- 6. Catheter-Associated Urinary Tract Infection
- 7. Vascular Catheter-Associated Infection
- 8. Manifestations of Poor Glycemic Control
- 9a. Surgical Site Infection, Mediastinitis Following Coronary Artery Bypass Graft
- 9b. Surgical Site Infection Following Certain Orthopedic Procedures
- 9c. Surgical Site Infection Following Bariatric Surgery for Obesity
- 10. Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures

Evaluation of Present on Admission Indicator Reporting

To determine the effectiveness of the HAC program, including POA indicator reporting, on quality of care, CMS is undergoing an independent evaluation that includes the following components.

Tabulation of Claims. The evaluation includes a tabulation of the reporting of HACs and their POA indicator status from hospital claims. This information was published in the FY 2012 IPPS Proposed and Final Rules with links to additional information. The tabulations revealed that many HACs are relatively rare events and for most hospital stays, HACs are reported as present on admission.

Evidence-based Guidelines (EBGs) for Preventing HACs. For the Medicare statute requires that selected HACs be reasonably preventable through the application of evidence-based guidelines. An evaluation report identified current evidence-based guidelines for the ten selected HACs, one candidate HAC, and seven previously-considered candidate HACs. The report will be updated annually.

State Tracking of HACs. The State Tracking report provides a comprehensive review of the status of state government tracking of HACs. There are no federal standards for state reporting systems and no uniform list of reportable events or HACs. As of February 2011, 27 states and the District of Columbia enacted legislation to establish medical error, or adverse event, reporting systems. The majority of these publicly report only aggregate-level data. Thirty-two states have mandated reporting of HAIs, and of those, twenty-two states use CDC's National Healthcare and Safety Network (NHSN) for data collection. Most states with legislative mandated reporting systems hold individual hospitals accountable for their patient care performance. Sixteen states use collected data for both regulatory and voluntary patient safety improvement efforts. Federal regulations issued in 2011 prohibit Federal payments to States for any amounts expended for providing medical assistance for HCACs and also authorizes States to identify other provider-preventable conditions for which Medicaid payment would be prohibited. This report will be updated annually.

Incremental Cost of HACs. Preventable conditions and infections that are hospital acquired create a significant financial burden on both the Medicare program and Medicare beneficiaries. In FY 2009, CMS spent an additional \$135 million for Part A services on the selected HACs across the episode of care. Among the previously-considered candidate HACs, the estimated Part A incremental cost to CMS was \$510 million in FY 2009. For beneficiaries, the Part A incremental cost of the selected HACs was \$17 million across the episode of care, and the additional cost of the candidate HACs was about \$63 million.

Future Research. Fiscal Year 2011 was the second year of the evaluation. In FY 2012, research will continue in the areas of: determining the accuracy of the POA codes on the hospital claims; estimating the readmission rates resulting from HACs; estimating the incremental cost of HACs on Medicare reimbursements and Medicare beneficiaries

including Part B costs; and determining whether there are unintended consequences of HACs and the spillover effects of the Medicare HAC program on other healthcare payers.

Enhancements and Future Issues

Each year, through IPPS rulemaking, CMS has the opportunity to consider refinements to the HAC list and potential candidate conditions. This might include the consideration of additional categories of conditions, expansion of existing categories, and reconsideration of conditions that had previously been proposed but not selected. For example, the implementation of ICD-10 in FY 2014 will provide more specific coding information that would facilitate more precise identification of Hospital-Acquired Conditions. Additionally, stakeholders have suggested that water-borne pathogens be considered, that the surgical site infection (SSI) category be expanded, and that ventilator-associated pneumonia (VAP) and *S. aureus* septicemia be reconsidered. The ability to select additional conditions will depend on the development of evidence-based guidelines such that when those guidelines are followed, the conditions can be considered reasonably preventable. In addition, having the POA indicator as a part of the Medicare claims data will help facilitate identification of additional candidate HACs.

Consumer groups and the media have suggested that infections caused by MRSA and *C. difficile* be selected as HACs for the payment provision. Importantly, these infectious agents are directly addressed in part by the infectious conditions currently selected as HACs. For example, MRSA could be the etiologic agent for a vascular catheter-associated infection. However, the current coding for MRSA and *C. difficile* does not differentiate colonization from infection. As the diagnosis coding is refined, the ability to differentiate community from hospital-acquired infections improves, and evidence-based guidelines for the prevention of infectious agents are defined and enhanced. Accordingly, these infectious agents may be reconsidered as candidates for the HAC payment provision in future rounds of rulemaking.

Beginning in FY 2015, under changes to the Social Security Act made by Section 3008 of the Affordable Care Act (ACA), CMS will reduce payment for discharges from hospitals that have risk-adjusted HAC rates in the top quartile of applicable hospitals. In addition, the ACA requires the Secretary to undertake a study and a Report to Congress on extending the HAC-payment policy to other types of providers. The Report to Congress is due during 2012. It will include recommendations for such legislation and administrative action as the Secretary determines is appropriate.

Collection of the present on admission indicator could provide important information, not only for Medicare payment, but also for enhancing public health. Researchers could use present on admission data from Medicare hospital claims independently or merged with data from other states or the private sector to explore policy initiatives and refinements, such as for risk adjustment of quality measurement data, tracking incidence of conditions in the community and in hospitals, or support better healthcare decision making by consumers and professionals.

C. Hospital Pay-for-Reporting

Hospital pay-for-reporting is another approach that CMS has adopted to achieve high quality and more efficient healthcare. This initiative is designed to equip consumers with quality of care information to make more informed decisions about their healthcare, while encouraging hospitals and clinicians to improve the quality of inpatient care. In December 2002, the HHS Secretary announced a partnership with several collaborators to promote hospital quality improvement and public reporting of hospital quality information. These collaborators included the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, The Joint Commission, the National Quality Forum, the American Medical Association, the Consumer-Purchaser Disclosure Project, the American Association of Retired Persons, the American Federation of Labor-Congress of Industrial Organizations, AHRQ, as well as CMS and others.

Initially, subsection (d) hospitals were incentivized to submit data on a starter set of ten quality measures. Hospitals that did not submit data received a reduction of 0.4 percentage points to their annual payment update (also known at the time as the market basket update) for each of FYs 2005 through 2007. The reduction to the annual payment update has subsequently increased from 0.4 to 2.0 percentage points for FY 2007 through 2014. Beginning in FY 2015, the payment reduction becomes one quarter of the applicable percentage increase for the fiscal year. For FY 2008, CMS required that hospitals submit data on 27 quality measures including a number of infection-related measures and encompassing the following conditions: acute myocardial infarction, heart failure, pneumonia, surgical care improvement, 30-day mortality rates for acute myocardial infarction and heart failure patients, and patients' experience of care through the Hospital Consumer Assessment of Health Providers and Systems patient survey.

For FY 2009, CMS finalized a total of 30 quality measures including (1) two new Surgical Care Improvement Project process of care measures and (2) a new outcome of care measure 30-day mortality rate for pneumonia patients.

For FY 2010, CMS finalized a total of 44 quality measures, including (1) nine AHRQ Patient Safety Indicators and Inpatient Quality Indicators that have been endorsed by the National Quality Forum; (2) a National Quality Forum-endorsed structural measure, Participation in a Systematic Database for Cardiac Surgery; and (3) three NQF-endorsed readmission measures related to Heart Failure, Pneumonia, and Acute Myocardial Infarction.

For FY 2011, CMS adopted two chart abstracted Surgical Care Improvement Project (SCIP) measures and eight Hospital Acquired Condition measures.

The SCIP measures are as follows:

• Timing of receipt of initial antibiotic following hospital arrival for patients with pneumonia;

- Blood culture performed before first antibiotic received in hospital for patients with pneumonia;
- Appropriate initial antibiotic selection for patients with pneumonia;
- Prophylactic antibiotic received within one hour prior to surgical incision;
- Prophylactic antibiotics discontinued within 24 hours after surgery end time;
- Prophylactic antibiotic selection for surgical patients;
- Cardiac surgery patients with controlled 6 AM postoperative serum glucose;
- Surgery patients with appropriate hair removal;
- Postoperative urinary catheter removal on post-operative day 1 or 2; and,
- Perioperative temperature management.

The Hospital Acquired Condition measures related to HAIs include catheter-associated urinary tract infection (CAUTI) and vascular catheter-associated infection (VCAI).

For FY 2012, CMS is collecting a total of 55 quality measures, including the eight HAC measures; the ten CMS-calculated AHRQ and Quality Patient Safety Indicators and Inpatient Quality Indicators that have been endorsed by the National Quality Forum; and the HAI measure of central line-associated bloodstream infection (CLABSI).

CMS has aligned with CDC to publicly report on Hospital Compare data reported to NHSN. CMS began requiring hospitals participating in the Hospital IQR Program to report CLABSI data to the NHSN beginning with January 1, 2011 discharges. Beginning with January 2010 discharges, CMS will also require hospitals participating in the Hospital IQR Program to report SSI data on the NHSN.

The agency is also requiring that hospitals use the NHSN infrastructure and protocols, as well as the specifications (available at

http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf) to report the measures for Hospital Inpatient Quality Reporting program purposes.

For FY 2015, CMS has adopted new CDC/NHSN-based HAI measures to the Hospital Inpatient Quality Reporting program for payment determination:

- MRSA Bacteremia;
- Clostridium difficile; and,
- Healthcare Personnel Influenza Vaccination.

CMS anticipates proposing to add the following three NHSN measures to the Hospital Inpatient Quality Reporting program in the future:

- VAP
- Post-Procedure Pneumonias, and
- Multi-Drug Resistant Organisms VRE, *Klebsiella*, *Acinetobacter*.

D. CMS Demonstration Projects

Medicare has a long and successful history of developing program initiatives through its demonstrations. At any given time, CMS has over two-dozen demonstrations in its portfolio. The implementation of these demonstrations has frequently provided the agency with practical lessons on policy tradeoffs and objectives, details related to operations of a specific pilot program, and unanticipated issues related to recruiting and engaging demonstration participants. Formal evaluations also play a critical part of any demonstration. CMS generally contracts with outside researchers to conduct independent evaluations of each demonstration project. Evaluations are carefully developed, often using randomly-assigned control groups and other sophisticated evaluation techniques, to report the results of the demonstrations to CMS and other executive branch leadership, Congress, and the public.

Several demonstration projects conducted by CMS test methods to improve the quality of healthcare. One of the most important of these is the Premier Hospital Quality Incentive Demonstration, with 250 about hospitals in 38 states in collaboration with Premier, Inc., which operates a large quality measurement and improvement operation. This demonstration ran from October 2003 through September 2009. The demonstration measured and provided bonus incentives for improving quality of care in six clinical areas: acute myocardial infarction, pneumonia, heart failure, coronary artery bypass graft, and hip and knee replacement, and Surgical Care Improvement Project (SCIP). During the six years of operations, the demonstration hospitals improved their quality of care in the six clinical areas by 18.6% percent on average.

CMS extended the demonstration for a second three-year period which ended in September 2009. New quality measures, including all of the SCIP measures, had been added for testing.

The SCIP measures are also included in two related demonstrations, the Medicare Gainsharing Demonstration and Physician Hospital Collaboration Demonstration. These two demonstrations were designed to study whether incentives for collaborative arrangements between hospitals and physicians can improve the quality and efficiency of care provided to Medicare beneficiaries. These SCIP measures include the use of prophylactic antibiotics before surgical incisions, the proper selection of antibiotics, proper surgical preparation to avoid infections, and discontinuation of the antibiotics on schedule to reduce antibiotic resistant bacteria strains. CMS tracks quality of care among participating hospitals to ensure that the demonstration results in improved quality of care.

The SCIP measures are also included in the Acute Care Episode Demonstration to improve inpatient quality of care. Medicare pays up to 15 hospitals in Texas, Oklahoma, Colorado, and New Mexico a "global fee" for select cardiac and orthopedic procedures. The global fee is a bundled payment for both hospital and physician costs, including the surgeon, consulting physicians or specialists, radiologists, anesthesiologists, or other physicians included in the care of the patient. Participating hospitals and physicians are

permitted to use gain-sharing to improve incentives for collaboration. This demonstration is intended to improve internal hospital cost efficiency and quality of care, reduce costs for Medicare, and improve transparency of information for beneficiaries. Quality will be measured through a series of reported process and outcome measures, including several that focus on surgical infections, such as selection and administration of antibiotics and deep sternal wound infection rate.

In all four Medicare demonstrations described above, CMS measures quality of care using available quality measures that will be monitored regularly to track progress toward improving quality. The measurement and evaluation of hospital-acquired infections are an important part of these evaluations, and the Medicare demonstrations program will continue to include hospital-acquired infection measures, as they are developed, standardized, available, and appropriate for use in future demonstration projects.

E. Hospital Value-Based Purchasing Plan Report to Congress

With the 2010 passage of ACA, CMS was able to launch the Hospital VBP program to link hospital payment under the IPPS to quality outcomes under the Medicare Program. Section 3001 of the Affordable Care Act authorizes the establishment of a hospital value-based purchasing payment program for subsection (d) hospitals under which payments will first be applied beginning with October 1, 2012 discharges.

CMS developed a plan to implement Medicare Hospital VBP in 2006 and 2007. On November 21, 2007, CMS submitted a Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program (the Plan). The Plan was built on the current Hospital IQR Program discussed above and establishes a performance-based Medicare IPPS hospital payment adjustment. Under VBP, a portion of hospital base operating DRG payment amount will be contingent on actual performance, rather than simply on a hospital's reporting of measurement data. Under the statute, VBP performance measures must include hospital-associated infection rates, as measured by the prevention metrics and targets established in the National Action Plan to Prevent Healthcare-Associated Infections (or any successor plan).

Hospital Value-Based Purchasing provides powerful incentives - both financial and non-financial - for discouraging hospital-acquired infections. Payments to higher performing hospitals will be larger than those for lower performing hospitals, providing financial incentives to drive improvement. Public reporting of performance on Medicare's Hospital Compare website will provide non-financial incentives to encourage hospital performance improvement. Hospital Compare will be discussed in further details in Section 3.

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¹⁷ U.S. Department of Health, Centers for Medicare and Medicaid Services. Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program. November 21, 2007. (www.cms.hhs.gov/AcuteInpatientPPS/downloads/HospitalValue-basedPurchasingPlanRTCFINALSUBMITTED2007.pdf, accessed November 22, 2010)

Hospital Value-Based Purchasing and the Affordable Care Act

Starting with the FY 2013 Medicare payment determination, hospital performance on measures covering five clinical topics (acute myocardial infarction, heart failure, pneumonia, SCIP, and the Hospital Consumer Assessment of Health Providers and Systems Survey) will be used to make payments adjustments to participating hospitals. Hospital VBP measures must be included in the Hospital Inpatient Quality Reporting Program and publicly reported on Hospital Compare for at least one year prior to the performance period for a given fiscal year payment determination. CMS finalized proposed measures, performance periods, and other program requirements for the FY 2013 Hospital VBP Program through rulemaking in the Spring of 2011.

Under Hospital Value-Based Purchasing Program, participating hospitals are scored based on their demonstrated improvement or high levels of achievement. The Affordable Care Act also mandated a five-year phased approach to link payment to quality under the Hospital VBP Program by increasing the percentage of the base operating Diagnosis Resource Group payment at risk from one percent in FY 2013 to two percent by FY 2017. Under Hospital VBP, payments made to high-performing hospitals will generally be larger than those made to lower performing hospitals. The Hospital VBP Program provides financial incentives to drive improvements in clinical quality, patient-centeredness, and efficiency.

CMS expects that in implementing the Hospital VBP, the measures used for the Hospital VBP Program financial incentive and public reporting will continue to evolve. The agency is considering whether to propose for program adoption domain of measurement related to patient safety is likely to be expanded over time to include measures addressing the priority infections previously identified in the 2009 Action Plan.

F. Hospital Readmission Reduction Program

In its June 2007 Report to Congress, the Medicare Payment Advisory Commission has identified seven conditions that make up almost 30 percent of Medicare spending on readmissions. These seven conditions are heart failure, chronic obstructive pulmonary disease, pneumonia, acute myocardial infarction, coronary artery bypass graft, percutaneous transluminal coronary angioplasty, and other vascular conditions. To meet the Deficit Reduction Act (2005)'s requirements related to the Hospital Inpatient Quality Reporting Program, CMS has developed readmission measures for 4 of the 7 conditions identified by the Medicare Payment Advisory Commission, including: acute myocardial infarction, heart failure, pneumonia, and percutaneous transluminal coronary angioplasty. Currently, CMS is actively working to develop readmission measures to address the other conditions identified by Medicare Payment Advisory Commission.

The Hospital Readmissions Reduction Program was established by Section 3025(a) of Affordable Care Act of 2010 to reduce payment to hospitals, beginning in FY 2013, that have excess readmissions based on the readmission measures endorsed by the National Quality Forum. These readmission measures pertained to acute myocardial infarction,

heart failure, and pneumonia. Under the Hospital Readmission Reduction Program, the Secretary, shall, to the extent practicable, expand the conditions of readmission measures subject to this payment adjustment beginning FY2015 as noted below:

"(B) EXPANSION OF APPLICABLE CONDITIONS – Beginning with fiscal year 2015, the Secretary shall, to the extent practicable, expand the applicable conditions beyond the 3 conditions for which measures have been endorsed as described in ... to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary" ACA Sec. 3025(a), adding new Sec. 1886(q)(5)(B) to the Social Security Act.

The Affordable Care Act prescribes a formula for determining the payment reduction, scheduled to begin in FY 2013. ACA limits the reduction to one percent in FY 2013, two percent in FY 2014, and three percent in FY 2015 and subsequent years. Certain adjustments within the Medicare IPPS, such as adjustments for outliers, indirect medical education, disproportionate share hospital and low volume, are not taken into account when determining the payment adjustment.

G. Physician Quality Reporting System

The Tax Relief and Health Care Act of 2006 required the establishment of a physician quality reporting system, including an incentive payment for eligible professionals who satisfactorily report data on quality measures for covered professional services furnished to Medicare beneficiaries during the second half of 2007. CMS initially named this program the Physician Quality Reporting Initiative (PQRI). PQRI was further extended and modified as a result of the Medicare, Medicaid, and State Children's Health Insurance Program Extension Act of 2007, the Medicare Improvements for Patients and Providers Act of 2008, and the Affordable Care Act of 2010. CMS changed the name of the program to the "Physician Quality Reporting System" in 2011. Through 2014, an eligible professional (or, for 2010 and subsequent years, a group practice) who satisfactorily reports data on quality measures may qualify to earn a Physician Quality Reporting System incentive payment, based on a percentage of the Secretary's total estimated allowable Medicare Part B charges for covered professional services furnished during a specified reporting period.

An eligible professional who satisfactorily reported Physician Quality Reporting System quality measures data for 2007 or 2008 could qualify to earn an incentive payment equal to 1.5 percent of the total estimated Medicare Part B Physician Fee Schedule (PFS) allowable charges for covered professional services furnished during the applicable reporting period selected by them. For 2009 and 2010, the incentive payments for satisfactory payments where equal to 2.0 percent of the Secretary's total estimated Medicare Part B PFS allowed charges for covered professional services furnished by the eligible professional (or group practice) during the applicable reporting period. The applicable quality incentive payments percentages decrease to 1.0 percent for 2011 and 0.5 percent for 2012, 2013, and 2014.

Eligible professionals (and group practices) that do not satisfactorily report quality measures under the Physician Quality Reporting System will be subject to a negative payment adjustment beginning in 2015. The payment adjustment starts as a 1.5 percent reduction in the fee schedule amount for covered professional services furnished during 2015 and increases to a 2.0 percent reduction for 2016 and each year thereafter.

Since its inception, the Physician Quality Reporting System has grown from a claims-based quality measure reporting program, with 74 quality measures available for reporting by 2007, to a program with several different reporting options from which an eligible professional can select to qualify for a Physician Quality Reporting System incentive payment. Under the 2011 Physician Quality Reporting System, eligible professionals can participate individually by reporting data on the Physician Quality Reporting System quality measures via claims, a qualified registry, or a qualified electronic health record (EHR) or participate as part of a group practice under one of the group practice reporting options (GPRO I and GPRO II). The number of individual quality measures available has increased to nearly 200 measures and 14 measures groups and there are 26 measures available for reporting under the GPRO I group practice reporting option.

Under the 2011 Physician Quality Reporting System Program, there are six measures that can be reported by eligible professionals that address the reduction of HAIs. These measures include the following:

- Perioperative Care: Timing of Antibiotic Prophylaxis Ordering Physician;
- Perioperative Care: Selection of Prophylactic Antibiotic First OR Second Generation Cephalosporin;
- Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures);
- Perioperative Care: Timely Administration of Prophylactic Parenteral Antibiotics;
- Prevention of Catheter-Related Bloodstream Infections: Central Venous Catheter Insertion Protocol; and,
- Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures)

While additional measures can certainly be developed to address HAIs, it is important to remember that the Physician Quality Reporting System is a physician-based reporting program. Although many eligible physicians practice in a hospital setting, new measures would more likely be structural measures, or implemented or collected at the hospital level. For example, a measure could look at how often healthcare providers wash their hands between patient encounters and following procedures or interventions.

H. Physician Feedback Program and Value-Based Payment Modifier

The Physician Feedback /Value-Based Payment Modifier is a Physician Value-Based Purchasing Program, whose goal is to improve Medicare beneficiary health outcomes and experience of care by using payment incentives and transparency to encourage higher

quality, more efficiently provided healthcare services. The Physician Feedback Program was established by section 131(c) the Medicare Improvements for Patients and Providers Act of 2008, which requires CMS to provide confidential reports to physicians (and as determined appropriate by CMS, to groups of physicians) that measure the amount of resources involved in furnishing care to Medicare beneficiaries. Information on the quality of care furnished by the physician may also be included. The program has been developed in phases.

Phase I of the Program was completed in 2009 with approximately 310 reports sent to randomly selected physicians in 12 metropolitan areas across the United States. Formative testing of the reports with physicians, as well as retrospective analyses of the data used in Phase I informed CMS's plans for Phase II of the Program.

Phase II of the Program was completed in 2010 and CMS provided reports to 36 group practices and approximately 1,650 individual practitioners affiliated with those groups in the 12 geographic areas identified in Phase I. Phase II reports also included clinical quality of care data, in addition to total per capita resource use information. In addition, CMS also provided condition-specific per capita resource use information for five high-cost, high-volume conditions, including congestive heart failure, chronic obstructive pulmonary disease, coronary artery disease, diabetes and prostate cancer.

In Phase III of the program, CMS disseminated in September, 2011 combined quality and resource use reports to the large medical group practices (each with 200 or more physicians) that participated in the Physician Quality Reporting System Group Practice Option (GPRO-1). We chose these medical groups because their quality performance could be compared on the common set of 26 quality measures included in the Physician Quality Reporting System GPRO-1 reporting tool. We also compared the group practices on measures of preventable hospital admission for six ambulatory care sensitive conditions including diabetes, heart failure, bacterial pneumonia, chronic obstructive pulmonary disease, dehydration, and UTI. The resource use section of these reports compared the 35 groups on total per capita cost information and per capita cost information on four conditions prevalent in the Medicare population including diabetes, chronic obstructive pulmonary disease, heart failure and coronary artery disease. Early in 2012, we also intend to disseminate Physician Feedback reports to approximately 20,000 Medicare fee-for-service physicians in a four state region: Iowa, Kansas, Missouri, and Nebraska.

The Affordable Care Act of 2010 contained two provisions relevant to the Physician Feedback program. Section 3003 continues and expands the confidential feedback program. In late 2012, CMS plans to undertake a significant effort to scale up distribution of reports to physicians nationally. Additionally, section 3003 requires the development of a Medicare-specific episode grouper so that physicians can be compared on episode-based costs of care.

Section 3007 of the Affordable Care Act requires CMS to apply a separate, budget neutral value-based payment modifier to the Physician Fee Schedule payment formula

based upon a physician's or a physician group's quality of care furnished compared to cost during a performance period. Quality of care and cost must be evaluated based on a composite of quality and cost measures. The payment modifier applies application to the Physician Fee Schedule beginning January 1, 2015, for specific physicians and medical groups. By January 1, 2017, CMS must apply the value modifier to the physician fee schedule for all physicians and physician groups. In 2013, CMS will implement program parameters for the value modifier through rulemaking.

We view section 3003 and section 3007 as complementary, as we expect the work done for the physician feedback program under to inform implementation of the payment modifier.

Many of the measures of quality and resource use that we use in other quality programs and measures included in the physician feedback reports will be the foundation for the composite of measure that we will use for purposes of the value modifier. Section 3007 mandates that CMS publish the measures of quality of care and costs for the value modifier by January 1, 2012. CMS has emphasized in its Physician Fee Schedule rulemaking in 2012 the connection between the Physician Quality Reporting System and the value modifier. We have also placed considerable importance on enhancing the current quality measures for the Physician Quality Reporting System and the Health Information Technology for Economic and Clinical Health Act (HITECH)/EHR Incentive programs by planning to develop outcomes measures that can capture care coordination, transitions of care, and other more complex interactions among providers such as those related to HAIs. We anticipate that we will continue to modify and enhance the composite measures for quality of care and resource use for the value modifier as additional quality measures become available.

The process of developing a value modifier and feedback reports that are fair, meaningful, and actionable for physicians is evolutionary. CMS will emphasize transparency, collaboration with stakeholders, and outreach through physician groups and specialty societies, public listening sessions, and use of the Medicare physician fee schedule rulemaking process.

The remainder of this section describes the use of VBP as a tool to combat HAIs in post-acute care settings and through care coordination.

I. Quality Reporting for Long-Term Care Hospitals, Inpatient Rehabilitation Facilities and Hospice Programs.

Section 3004 of the Affordable Care Act establishes new quality reporting programs for long-term care hospitals (LTCH), inpatient rehabilitation facilities (IRF) and hospice programs. Inpatient rehabilitation facilities may voluntarily report quality indicators at this time, but few do consistently. Currently, there are no federally-required quality reporting programs that apply to long term care hospitals, inpatient rehabilitation facilities and hospice programs.

Starting in October 2012, under the new quality reporting programs established by section 3004, IRFs and LTCHs will be required to report new and worsening pressure ulcers and CAUTI events. Additionally, LTCHs will be required to report CLABSI events. Hospice programs will, starting in October 2012, be required to report data on Quality Assessment and Performance Improvement and End Result Outcome Measures. Failure to report quality data will result in a two percent payment update penalty starting FY 2014. IRFs and LTCHs will report their infection event data to the CDC through NHSN. The CDC will report aggregated provider-level data to CMS, for those providers who elect to have their quality data reported to CMS. IRF quality data for new or worsening pressure ulcers will be electronically reported to CMS through a modified IRF form. LTCH quality data for new or worsening pressure ulcers will be electronically reported to CMS through a newly developed LTCH-CARE (Continuity Assessment Record & Evaluation) form. Hospice quality data will be electronically reported to CMS in a format to be determined.

J. Value-Based Purchasing for Skilled Nursing Facilities and Home Health

Quality measures that target HAIs may serve as the basis of VBP programs for skilled nursing facilities and home health agencies in the future. Currently, quality measures are publicly reported on Nursing Home Compare websites. Quality measures publicly reported for skilled nursing facilities and nursing homes include two prevalence measures of pressure ulcers (among long-stay residents), and percentage of residents with pressure ulcers that are new or have not improved (among short-stay residents). Both pressure ulcer measures are reported on the Nursing Home Compare website. The measures of percentage of residents who have a urinary tract infection and percentage of residents who have had an indwelling catheter inserted are also reported for long-stay nursing home residents on the Nursing Home Compare website. Additionally, percentage of residents who were appropriately offered the seasonal influenza and the pneumococcal vaccine are reported for both short- and long-stay residents. Home Health Compare reports quality measures, including one outcome measure (Improvement in urinary tract infections) and two Potentially Avoidable Event measures (Development of urinary tract infections and Emergent Care for Wound Infections). Measures of how often the home health agencies determined if their patients received the flu and pneumonia vaccines are also publicly reported. Application of metrics to assess care processes and achievement of CAUTI, C.difficile and Staphylococcal transmission avoidance is highly dependent on the development and implementation of cross-cutting measures and data collection mechanisms.

K. Shared Savings/Accountable Care Organizations

Section 3022 of the Affordable Care Act directs the Secretary of HHS to "establish a shared savings program ... that promotes accountability for a patient population and coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery." The Shared Savings Program is a voluntary program that defines an ACO as a group of healthcare providers and suppliers that agree to become accountable for the

quality, cost, and overall care of Medicare beneficiaries enrolled in the traditional fee-forservice program who are assigned to it. The ACO qualifies for shared savings by meeting specific cost and quality benchmarks. The program must be established not later than January 1, 2012.

The statute states that an ACO may be formed by a variety of different groupings of Medicare-enrolled providers and suppliers, as determined appropriate by the Secretary and may or may not include an inpatient facility.

Additionally, there are certain criteria that an ACO must meet to become eligible for the Shared Savings Program, such as agreeing to participate for not less than three years, having a formal legal structure, including primary care providers sufficient for the care of the number of assigned Medicare fee-for-service beneficiaries (not less than 5000 beneficiaries), and defined processes to promote evidence-based medicine.

Accountable Care Organization Performance Assessment and Incentive Payment Model

An ACO qualifies for shared savings by meeting certain quality and cost benchmarks. The Affordable Care Act requires that the Secretary determine appropriate measures to assess the quality of care furnished by the ACO. An ACO must meet quality performance standards established for these measures to be eligible to share in any savings realized. The measures adopted in the final rule to assess quality performance were developed through extensive review of data quality and previously-conducted research, internal discussion, engagement of public stakeholders through multiple listening sessions and public comment on the proposed rule, and coordination with national quality organizations.

While maintaining focus on the three-part aim of better care for individuals, better health for populations, and lowering growth in expenditures, the development of quality performance measures is guided by the goal of addressing, as feasible, all six Institute of Medicine aims for improvement. In keeping with these aims, standards for achievement should indicate that an ACO has provided care that is safe, timely, patient-centered, effective, efficient, and equitable.

The Affordable Care Act specifies that if an ACO meets the quality performance standards, savings are realized only if it reduces growth in total Parts A and B per capita costs of the Medicare fee-for-service beneficiary population assigned to it to lower than its benchmark per capita costs. Since HAIs require additional treatment and increase estimated per beneficiary costs, it is less likely that the ACOs participating in the Shared Savings Program will have savings below the cost benchmark and qualify to receive an incentive payment unless HAIs are controlled in the assigned population.

ACOs that participate in the Shared Savings Program and other ACO initiatives are motivated to reduce HAIs because they will be eligible to receive sharing savings only if per capita beneficiary costs are reduced to below the estimated benchmark.

Future Direction of the Shared Savings Program

The statute requires that the Secretary seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both, for the purposes of assessing quality of care. Measures of healthcare quality, which could include addition or expansion of HAI measures, may be added to the Shared Savings Program over time. In addition, the quality performance standards may be raised in future years, encouraging providers to place more emphasis on improving quality and, including avoiding costly and preventable HAIs, to qualify for shared-savings incentives.

L. Recommendations and Action Plan for Value-Based Financial Incentives

CMS currently has the statutory authority to adjust hospital MS-DRG payments for selected conditions under the HAC payment provision. CMS has selected CAUTI, VCAI, and certain SSIs for non-payment under the HAC provision when those infections are acquired during hospitalization. Other infections, like ventilator-associated infections, MRSA, *C. difficile*, and other SSIs may be reconsidered as candidates for the HAC payment policy during future rounds of rulemaking. However, the ability to select additional conditions will depend on the development of evidence-based guidelines and published literature supporting the conclusion that the conditions can be considered reasonably preventable when the guidelines are followed.

CMS also has the statutory authority to collect and publicly report hospital quality data under the Hospital Inpatient Quality Reporting Program. The program measures hospital compliance with reporting an increasing number of infection control and prevention best practices, including measures developed by SCIP. Adoption of additional measures occurs through rulemaking, which occurs annually with a proposed rule published in the Federal Register in the spring and a final rule published in August.

CMS has used the experience from the HAC payment provision, the Hospital Inpatient Quality Reporting Program measurement and public reporting program, and various performance-based payment demonstration projects to inform the development of the Hospital VBP Program. CMS believes that the Hospital VBP Program is a more sophisticated approach to VBP than the current HAC and pay-for-reporting approaches. Risk-adjusted rates of infection prevention interventions and outcomes over time for infections like VAP, MRSA, or *C. difficile* may be proposed through the rulemaking process to create a patient safety domain of measurement, which will count toward the calculation of a hospital's VBP incentive payment for all diagnosis related groups.

Thus, the infection prevention and outcomes measures in the patient safety domain could become a subset of the total performance score of the Hospital Value-Based Purchasing Program. Scores for the individual infection prevention and outcomes measures, aggregate infection measures, and patient safety domain could be posted on the Hospital Compare website, along with the scores for the other domains and the total performance score, and could serve as one type of "scorecard" for infection prevention and outcomes.

The next section focuses on public reporting, another tool used by federal health agencies to prevent and reduce HAIs.

IV. Transparency and Associated Incentives

A. Introduction

Transparency is a broad-scale initiative intended to equip consumers with quality of care information to make informed decisions about their healthcare, while encouraging institutions and clinicians to improve the quality of care. Transparency in healthcare facilitates improvement of performance, efficiency, and quality by providing facilities and physicians with information for benchmarking.

Public reporting enhances accountability in healthcare by increasing the transparency of quality data. Providing reliable quality and cost information enhances decision-making by patients and stakeholders at the local, regional, and national levels. Professionals are more likely to join the staff of a high performing hospital. Choice leads to incentives at all levels and motivates the entire system; improvements take place as providers compete. This section provides detailed discussions on federal efforts in addressing HAIs through public reporting of hospital and physician performance.

B. Hospital Compare

Hospital Compare (www.hospitalcompare.hhs.gov) is a consumer-oriented website that provides information on how well hospitals provide care to their patients with certain medical conditions, including care related to the prevention of certain infections. Hospital Compare publicly reports hospital performance data in a consistent, unified manner to ensure public availability of credible information about the care delivered in the nation's hospitals.

The effort to publicly report processes of care and outcome measures furthers the goal to improve the quality and transparency of hospital care by giving the public and healthcare professionals better access to important hospital data. These quality measures are one approach to evaluate how well a hospital provides care for its patients. By making this information available, CMS is meeting two of the Secretary's four cornerstones for Value-Driven Health Care, that is, to measure and publish quality and price information. Hospital Compare allows consumers to evaluate how hospitals are delivering care to their patients through nationally standardized process of care and outcome measures for individual hospitals. This information helps inform consumers who are selecting a hospital for their medical care.

CMS launched the Hospital Compare tool on March 31, 2005. The measures currently reported on Hospital Compare include the measures that are reported under the Hospital Inpatient Quality Reporting Program (Hospital pay for reporting) and additional measures that many hospitals voluntarily report. A number of these measures are related to

infections: three of them are related to the prevention of surgical infections, seven measures to pneumonia care, and one to pneumonia outcomes.

Ten questions from a standardized survey of patient perspectives of their hospital care, known as Hospital Consumer Assessment of Healthcare Providers and Systems, are also reported the Hospital Compare site. Public reporting of standardized measures on patients' perspectives of the quality of hospital care encourages consumers and their physicians to discuss and make informed decisions on acquiring the best hospital care, and increases the public accountability of hospitals.

On April 1, 2011, CMS publicly reported the following eight HAC measures through a downloadable data file with a link on the Hospital Compare site and on October 13, 2011, these eight measures were incorporated into the main report on Hospital Compare. These eight measures were selected because they incur high costs to the Medicare program or because they occur frequently during inpatient stays for Medicare patients:

- 1. Foreign Object Retained After Surgery
- 2. Air Embolism
- 3. Blood Incompatibility
- 4. Pressure Ulcer Stages III & IV
- 5. Falls and Trauma:
 - Fracture
 - Dislocation
 - Intracranial Injury
 - Crushing Injury
 - Burn
 - Other injuries
- 6. Catheter-Associated Urinary Tract Infection
- 7. Vascular Catheter-Associated Infection
- 8. Manifestations of Poor Glycemic Control

The HAC public reporting shows the number of times a HAC occurred for Medicare fee-for-service patients between October 2008 and June 2010. The data for the HAC public reporting show that rates for infection were relatively common, with about 45 percent of hospitals reporting at least one blood or urinary tract infection developed during the hospital stay. Nationwide, a blood or urinary tract infection was reported once for every 3,300 discharges. CMS has also publicly reported these measures on the official CMS website (https://www.cms.gov/HospitalQualityInits/06_HACPost.asp) since March 31, 2011.

The public reporting of the HAC measures represents a significant milestone for CMS's efforts in improvement quality of inpatient care for Medicare beneficiaries. For the first time, Medicare patients can see how often hospitals report serious conditions that develop during an inpatient hospital stay and possibly harm patients.

CMS also incorporated the following AHRQ Patient Safety Indicators and Inpatient Quality Indicators into the main report of Hospital Compare on October 13, 2011:

- PSI 90 Composite Patient Safety for Selected Indicators
- PSI 04 Death Among Surgical Inpatients with Serious Treatable Complications
- PSI 06 Iatrogenic Pneumothorax
- PSI 11 Postoperative Respiratory Failure
- PSI 12 Postoperative Pulmonary Embolism or Deep Vein Thrombosis
- PSI 14 Postoperative Wound Dehiscence
- PSI 15 Accidental Puncture or Laceration
- IQI 91 Composite Mortality for Selected Conditions
- IQI 19 Hip Fracture Mortality
- IQI 11 Abdominal Aortic Aneursym (AAA) Repair Mortality

CMS worked with major stakeholders, like hospitals, consumer groups, employers, payers, and other government agencies to make HAC data accessible to the public in meaningful, relevant, and easily understood ways that encourage healthcare quality improvement. In October 2011, CMS incorporated the AHRQ Patient Safety Indicators and Inpatient Mortality Indicators as well as the HAC measures into the *Hospital Compare* framework.

Public reporting of standardized measures on patients' perspectives of the quality of hospital care encourages consumers and their physicians to discuss and make informed decisions on acquiring the best hospital care, and increases public accountability of hospitals.

Hospital Compare provides tools to incentivize hospitals to increase transparency at the system level. There is evidence that public reporting impacts hospital reputation. Hospital leadership is concerned about reputation as this may in turn impact staffing, endowments, and other charitable giving (if non-profit), branding, local political standing, and long-term market share. A hospital performing well on Hospital Compare could strengthen a community's reputation, attracting patients, physicians, and clinical staff.

Recommendations and Action Plan

Each year, CMS continues to add new measures to Hospital Compare. These enhancements are part of HHS' ongoing commitment to increased healthcare transparency. CMS added 19 new measures for the FY 2011 Hospital IQR program. The inclusion of these additional measures will encourage hospitals to strengthen patient safety. As measures are developed for hospital-associated infections related to CAUTI, VCAI, VAP, SSIs, MRSA, and *C. difficile*, they may be added to the Hospital Compare website. The addition of hospital-associated infection measures to Hospital Compare could increase awareness and educate consumers as well as continue to hold hospitals and other providers accountable for providing better and more efficient care.

The transparency provided by setting-specific Compare sites like Hospital Compare could be extended by developing a *Cross-setting Compare site* that reports cross-setting quality measures for acquired infections regardless of site of origin. Cross-setting data would support a "systems" approach to quality reporting and problem resolution of life threatening infections that may be difficult to attribute to a particular setting.

C. Physician Compare

Background

Section 10331 of the Affordable Care Act (2010) requires CMS to establish a Physician Compare website by January 1, 2011 that contains information on physicians enrolled in the Medicare program and other eligible professionals who participate in the Physician Quality Reporting System. By no later than January 1, 2013 (and for reporting periods beginning no earlier than January 1, 2012), CMS is required to implement a plan to make information on physician performance publicly available through Physician Compare.

In implementing the Physician Compare website, the Secretary shall take several statutory requirements into consideration. In particular, the Secretary is required to establish processes, to the extent practicable, to ensure that 1) the data are statistically valid and reliable and provide an accurate and robust portrayal of performance, 2) appropriate attribution of care, 3) timely statistical performance feedback; 4) the data reflects the care provided to all patients; and 5) physicians have a reasonable opportunity for prior review of any data made public. The Secretary is also required to ensure patient privacy; seek input from multi-stakeholder groups; and take into consideration the plan to transition to VBP.

To the extent practicable, the performance information on the Physician Compare website shall include the following: Measures collected under the Physician Quality Reporting System; an assessment of patient health outcomes and the functional status of patients; an assessment of continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use; an assessment of efficiency; an assessment of patient experience and patient, caregiver, and family engagement; an assessment of the safety, effectiveness, and timeliness of care; and other information as determined appropriate by the Secretary. A Town Hall meeting was conducted in October 2010 to solicit input from stakeholders to inform Physician Compare releases subsequent to initial January 1, 2011 release.

Recommendations and Action Plan:

CMS's plan for Physician Compare is as follows:

On December 30, 2010, CMS renamed the existing Healthcare Provider Directory Website as "Physician Compare." This site is primarily a consumer site and can be made to have flexible and logical pathways for consumers. January 2011, CMS added the

names of eligible professionals who satisfactorily reported 2009 Physician Quality Reporting System measures (this would replace the field that indicates whether an eligible professional participates in the Physician Quality Reporting System), which is required by the Medicare Improvements for Patients and Providers Act (2008).

In Spring 2011, CMS added the names of eligible professionals who were 2009 successful e-prescribers, as required by the Medicare Improvements for Patients and Providers Act. Data will be refreshed monthly and subsequent releases will occur semi-annually.

In July 2011, CMS published the 2012 Medicare Physician Fee Schedule proposed rule with proposed plan for reporting performance information based on 2012 reporting periods at the group practice level when the results are available, including the proposed measures. The Physician Quality Reporting System has two group practice reporting options that could be the source of the performance information. The Physician Quality Reporting System group practice measures could potentially be supplemented by limited set of claims-based measures (e.g., GEM measures) or physician level measures related to HAIs. Also in June 2011, CMS added the names of eligible professionals who are participating in the EHR incentive program, as required by the HITECH Act of 2009.

In November 2011, CMS published the 2012 Physician Fee Schedule final rule with plan for making performance information based on 2012 reporting periods publicly available, including the measures.

By Fall 2013, CMS plans to begin reporting performance information for group practices based on 2012 reporting periods.

V. Related Initiatives Addressing HAIs

A. Introduction

CMS has undertaken a number of other Medicare and Medicaid initiatives to combat HAIs. Within the Medicare program, quality improvement organizations provide direct provider support for reducing infections. The CDC has partnered with other federal and state health departments in the surveillance of HAIs and establishing guidelines on prevention. The Medicaid program is encouraging states to adopt the Medicare hospital-acquired conditions payment policy. It also funds the Transformation Grants, which include the goal of addressing central line infections for premature infants in the Neonatal Intensive Care Unit. Private organizations have also played an active role in consumer education on HAIs and advocacy.

B. Quality Improvement Organizations

The statutory mission of the Quality Improvement Organization program is to improve the effectiveness, efficiency, economy, and quality of services for Medicare beneficiaries. The Quality Improvement Organization Program is a network of organizations staffed

with physicians, nurses, technicians, and statisticians - experts in healthcare quality - with each quality improvement organization responsible for a U.S. state, territory, or the District of Columbia. Each of the 53 quality improvement organizations is governed by a performance-based cost reimbursement contract. The current contract, (the 10th Scope of Work, which continues for three years beginning August 2011) focuses on four aims: Improving Individual Patient Care, Beneficiary and Family-Centered Care, Integrating Care for Populations and Communities and Improving Health for Population and Communities while also focusing on the use of Learning and Action Networks to spread and sustain positive results. Within each of these aims, there are cross-cutting themes including promoting the use of Health Information Technology and Value-Driven Care.

The following discussion expands on the Patient Safety and Prevention Aims, which are more relevant to the HAIs focus of this report.

Patient Safety

Patient Safety efforts will reduce patient harm using proven evidence based quality improvement initiatives and tools to improve safety. This work will define improvement in patient safety as the reduction or elimination of patient harm that is more likely a result of the patient's interaction with the healthcare system than an attendant disease process. Work toward these goals will, by definition, increase the value of healthcare services by producing higher quality care for Medicare beneficiaries.

Quality improvement organization activities for the Patient Safety Theme will focus on five topics: reducing CLABSI, CAUTI, SSI and *C. difficile* infections in hospitals facility-wide, reducing rates of pressure ulcers and physical restraints in nursing homes, promoting best practices in nursing home and other long-term care settings and reducing adverse drug events through the use of a collaborative in partnership with HRSA, and promoting transparency through the Hospital Quality Reporting Program. The role of Survey and Certification has a strong potential to be further linked with quality improvement in the 10th SOW. For example nursing homes that have difficulty meeting the CMS survey and certification requirements will continue to have the opportunity to receive technical assistance from quality improvement organizations to assess areas for improvement and to evaluate and improve their performance.

In CMS's efforts to improve quality and avoid unnecessary costs to the Medicare Trust Fund, the Office of Clinical Standards and Quality, directs Quality Improvement Organization 10th Scope of Work's (SOW) Patient Safety to work in partnership with national, state, and local stakeholders in order to make a broad impact on HAI reduction rates. For example, CMS specifically partnered with CDC and AHRQ to coordinate HAI reduction programs, such as AHRQ's Comprehensive Unit-Based Safety Program (CUSP) for CLABSI and their CUSP for CAUTI nationwide initiatives in order to harness the power of shared resources and knowledge while avoiding duplicative efforts that can add to healthcare provider burden. In doing this, the QIOs will be able to take advantage of AHRQ-sponsored training sessions on CUSP principles geared both toward achieving, spreading and sustaining hospital-acquired CLABSI and CAUTI rate

reductions in the intensive care and non-intensive care unit settings. CMS has taken these and other HAI programs into strong consideration, including their standards, definitions and targets when determining QIO tasks in this body of work, not only to most strongly align nationwide but also to deliver a consistent message to those who care for patients. Facilities working with the QIO's in the 10th SOW will report their CLABSI, CAUTI and CDI rates into NHSN, which will help track the national picture for this effort. This data will also be available for feedback to facilities with higher infection rates helping to target certain performance improvement strategies to the areas of most need. The 10th SOW tries to align and strongly encourages partnerships with state health departments who for some, through CDC, American Reinvestment and Recovery and Affordable Care Act funding, we able to establish robust HAI prevention programs. These opportunities to form partnerships, develop work where none previously existed, spread reduction in the form learning and action networks and expand the work of infection prevention and reduction in our hospital beyond what the QIOs could capture alone.

Prevention

Prevention efforts will emphasize evidence-based and cost-effective care proven to prevent and/or slow the progression of disease. Work toward these goals will affect healthcare programs, products, policies, practices, community norms, and linkages and will produce higher quality of care for Medicare beneficiaries and significant cost savings. Over time, as disease is mitigated and its progression slowed through preventive measures such as early testing, immunization, and effective and timely intervention, the nation will see a healthier Medicare population emerge. This downstream impact will be most evident in the reduction of chronic kidney disease and decrease in the rate of progression to kidney failure.

C. Medicare Advantage Efforts

New Reporting Requirements for Medicare Advantage Organizations

As part of the proposed Medicare Part C reporting requirements effective January 1, 2009, CMS has been collecting measures that involve hospital-acquired conditions. Some of these measures involve infections, including: VCAI; CAUTI; SSI, mediastinitis, after coronary artery bypass graft; SSI following certain orthopedic procedures; and SSI following bariatric surgery for obesity. These data will be used in developing and reporting performance metrics for Medicare Advantage organizations. These measures are now subject to a yearly data validation audit process.

CMS has issued guidance to Medicare Advantage consistent with original Medicare rules effective October 1, 2008, in which specified preventable medical errors that occur at non-contracting hospitals will not be reimbursed. CMS will also be updating the "Medicare Advantage Payment Guide for Out of Network Payments" to reflect this guidance for all Medicare Advantage plans.

Medicare Advantage Quality of Care Requirements

The Medicare Advantage quality framework, including quality improvement programs, are described in the Medicare Advantage regulations, which currently require Medicare Advantage coordinated care plans to 1) have quality improvement programs, 2) initiate annual quality improvement projects and report results to CMS on these projects when they submit materials for their routine CMS audits; 3) have a chronic care improvement program; 4) report on annual activity of their Chronic Care Improvement Program when they submit materials for their routine CMS audits; and 5) report standardized performance measures specified by CMS annually.

These standardized performance measures include the Healthcare Effectiveness Data and Information Set, the Consumer Assessment of Healthcare Providers and Systems survey, and the Health Outcome Survey. The Healthcare Effectiveness Data and Information Set includes measures related to effectiveness of care, access/availability of care, and use of services; the Consumer Assessment of Healthcare Providers and Systems Survey includes measures which reflect experiences with the care received through the health plan; and the Health Outcome Survey includes measures which address changes in physical and mental health status.

Under the Medicare Advantage provider selection and credentialing requirements, Medicare Advantage plans are required to contract with providers who meet the credentialing requirements specified in the Medicare Advantage regulations. Included is a requirement that providers must be state-licensed and in compliance with all applicable state and federal requirements.

Under the Medicare Improvements for Patients and Providers Act of 2008, beginning in 2011, each Medicare Advantage Private Fee-for-Service and Medicare Savings Account plan must have an ongoing quality improvement program that meets the regulatory requirements. CMS is currently developing regulations to implement these new Medicare Improvements for Patients and Providers Act quality requirements for Private Fee-for-Service and Medicare Savings Account plans. For 2010, Medicare Savings Account and Private Fee-for-Service plan. Quality improvement reporting will only apply with respect to administrative claims data.

D. Centers for Disease Control and Prevention

While the mission of the CDC is broad and encompasses all of public health, the mission of the Division of Healthcare Quality Promotion (DHQP) is highly focused on the prevention of HAIs. Much of the recent success in preventing HAIs, for example reductions in CLABSIs, has been built upon the work of CDC spanning the last 30 years in learning how to detect, report , and prevent these infections. As a public health agency, CDC is involved in a continuum of activities that provide context for the recent involvement of sister agencies in HAI prevention and supports mutual roles in making HAI elimination a reality.

Epidemiology of HAIs

Identifying Opportunities for Incentives and Oversight and Evaluating their Impact. CDC leads and assists State Health Departments in field investigations to understand emerging and established HAIs. Because both the microbes and healthcare technology/delivery are both constantly evolving, CDC has a key role in identifying new prevention priorities. In addition to epidemiologists and subject matter experts, CDC has the only laboratory at the federal level for supporting such field investigations. These intramural resources and expertise make it possible to support states and CMS in developing content-specific guidance, assessment, and measurement tools. In addition, through the use of epidemiologic methods, CDC can quickly evaluate the impact of policy initiatives at both the state and federal levels, including the detection of unintended consequences. One example of such CDC-CMS partnership and collaboration working with state and local partners is the recent investigation of hepatitis transmission in Las Vegas Ambulatory Surgical Centers, in which the method of transmission was quickly identified, patients were notified and tested, and an Infection Control Worksheet was developed for use by state surveyors to prevent additional infections. As described elsewhere in this document, CDC then worked with CMS to pilot the tool in three states before ongoing national implementation as part of the state-based CMS certification process. An example of CDC assisting a state to evaluate the impact of a HAI policy initiative is CDC's assistance with Illinois to understand the impact of a state mandated prevention strategy for MRSA active surveillance testing to identify and isolate colonized patients.

Surveillance and Measurement of Healthcare-associated-Infections

The Yardstick for Incentives and Oversight. An important product from field investigations and early epidemiologic studies is the development of standardized case definitions and case finding techniques. CDC HAI surveillance definitions were first developed in the late 1980s and, along with methods for risk stratification, undergo regular evaluation for necessary revision based upon changes in underlying epidemiology or changes in healthcare technology. These were first developed for the legacy National Nosocomial Infection Surveillance System (NNIS), which in 2005 was replaced with the web-based NHSN. HAIs (outcomes) currently tracked in NHSN include CLABSIs, CAUTIS, VAP, SSI, dialysis access infections, colonization or infection with multidrugresistant organisms (e.g. MRSA), and C. difficile infections. Process measures reported in NHSN include central line-insertion practices, hand hygiene, and compliance with isolation precautions. Whereas NNIS was a solely voluntary system with approximate 300 acute care hospitals, NHSN has grown rapidly with the advent of state mandates for public reporting of HAIs. Currently there are approximately 5,000 acute care hospitals enrolled in NHSN and among 28 states with mandates for public reporting, with 22 and Washington, D.C. using NHSN to fulfill the mandates. In January 2011, acute care hospitals covered under the IPPS began reporting CLABSIs to NHSN in order to avoid the 2.0 percent reduction to their CMS update percentage increase (i.e. Hospital Inpatient Quality Reporting Program/pay-for-reporting; see http://www.qualitynet.org/). CLABSI rate data from this program will be reported, by hospital, on the Hospital Compare website. Plans for 2012 include the reporting of SSIs following hysterectomies and colon

surgeries through a similar mechanism via NHSN and presentation on the Hospital Compare Website. At present the NHSN is largely a manual data entry system but is moving quickly toward electronic data entry through a standards-based approach known as Clinical Document Architecture (CDA). Working with EHRs and surveillance software vendors, CDAs are being dev eloped to allow clinical and laboratory data as well as admission, discharge, and transfer data that have all been electronically captured in hospital systems to be, via standard HL7 messages and vocabulary, used in reporting HAI cases and denominators. Moreover, these electronic data can be leveraged to improve risk stratification. Already CDAs have been developed for the reporting of CLABSIs and denominators as well as the surgical case information that will be essential for risk stratifying SSI. Since the inception of NHSN and the decades of experience with NNIS, CDC has been at the forefront of understanding both modifiable and nonmodifiable risk factors for HAIs and how to apply these to a reporting system. Because NHSN relies on clinical and laboratory data rather than administrative data, a level of risk-stratification for outcome reporting is achievable that cannot be achieved with most other scalable approaches. Again, just as case definitions are evaluated for accuracy and overall suitability, so are risk- stratification methods the focus of ongoing research. Once adequate experience with a particular measure is attained and suitability for regional or national reporting is assured, CDC submits the measure to the National Quality Forumfor patient safety measure (PSM) endorsement. Current CDC surveillance definitions that are currently under review for PSM-endorsement by the National Quality Forum include CLABSI, CAUTI, and SSI. Because these different infections are risk-adjusted by a large and potentially growing number and variety of factors, a reporting parameter that is both rigorous and flexible is required to allow roll up of measures as envisioned under VBP. The Standardized Infection Ratio (SIR), based upon the concept of the Standardized Mortality Ratio, is just such a measure as it allows the comparison of performance to historic performance in the same risk strata. Thus a number of different factors can be used to risk stratify the population under surveillance and yet SIRs can still be either compared and/or "rolled up" across settings. Because the SIR is a ratio of observed to expected performance, however, movement and overall progress of "getting to zero" may be obscured; therefore there may still be a place for also presenting riskstratified rates where such presentation is still meaningful and yet feasible (i.e. as electronic data capture increases and models for risk stratification become increasingly complex and better at predicting underlying risk, the number of meaningful risk strata will increase).

National HAI Prevention Guidelines and HAI Research

The Foundations for Regulating Structure and Process. HICPAC is the only federal advisory committee for HAI prevention practices. Its mission includes the development of evidence-based and graded prevention guidelines for HAIs. High evidence grade prevention practices have formed the basis of highly successful prevention demonstration projects (i.e. CLABSI prevention in ICUs) and process measure national reporting systems (i.e. SCIP). CDC subject matter experts are not only responsible for shepherding guidelines through the writing and vetting process but also investigate the epidemiology and impact of prevention practices on these infections. As either evidence gaps or the

need for novel prevention strategies are identified, CDC plays a unique role in performing epidemiologic research to identify new prevention opportunities, early translational research to test novel strategies, or epidemiologic assessment of burden and likely impact for prioritization. In response to recent GAO recommendations CDC is currently performing a formal prioritization of its high evidence-grade recommendations. In addition, where prevention recommendations and evidence for their effectiveness appears strong, CDC performs epidemiologic research to assess compliance and works with states and other partners to improve compliance and reduce HAI rates (below). Once it has been demonstrated that groups or collaboratives of hospitals or other providers can reduce certain HAIs through application of HICPAC recommendations, CDC works with CMS to identify the types of incentives and oversight that can motivate more widespread high performance leading toward HAI elimination of HAIs.

Working with State Health Departments and Other Partners to Eliminate HAIs

Demonstrating that HAIs are Reasonably Preventable. The successful 64 percent reduction of CLABSI in Hospital ICUs involved in the Pittsburgh Regional Health Initiative is an early example of how CDC works with regional partners in prevention collaboratives. Now as a result of \$35 million in funding from the American Recovery and Reinvestment Act (2009) to state health departments, CDC is working with over 25 states conducting HAI prevention collaboratives with acute care hospitals (ranging in number from 8 to over 50) to prevent CLABSIs, CAUTIS, SSIs, MRSA, and C. difficile. These collaboratives work to share best practices for improving compliance with HICPAC high evidence grade, high-priority (based upon likely impact) or "core" prevention practices. Using NHSN, these collaborative hospitals HAI process and outcomes are measured and fed back to the hospitals and in various ways shared amongst hospitals. Additional guidance is given by CDC subject matter experts to include lower evidence grade ("supplemental") prevention practices for hospitals or collaboratives that are not achieving desired reductions in HAI outcomes despite high compliance with core recommendations. Other regional partners in this process include the state Quality Improvement Organizations and Hospital Associations. In this way CDC is leading partners at the regional level to both demonstrate preventability and reduce overall HAI burdens.

E. States Efforts

State Medicaid Program Efforts

The implementation of Medicare's hospital-acquired conditions payment policy left many State Medicaid Agencies wondering whether healthcare providers serving dually-eligible Medicaid and Medicare patients would simply attempt to pass unpaid Medicare bills to Medicaid as a secondary payer. Such action would effectively shift costs to States and, even more seriously, undermine any deterrent effect that the Medicare HAC payment policy would otherwise have.

Subsequently, ACA contained a Section 2702, to be effective on July 1, 2011, which required Medicaid to create a regulation similar to the Medicare HAC regulation, but which would cover all "Health Care Acquired Conditions" (HCAC). Medicaid was directed to review the response of State Medicaid programs to the issuance of the Medicare HAC regulation and to craft a federal law which would prohibit Medicaid payment to States for provider payments made for incidents defined in the regulation as Provider Preventable Events. Obviously, some of these events (as in the Medicare regulations) dealt with HAIs.

CMS reviewed the existing policies of the 21 State Medicaid programs that had already developed State regulations on the topic of HCAC. These regulations had already exceeded the scope of the Medicare regulations in the types of conditions covered, the care settings covered and the populations to which the HCACs applied. Many of the States had already gone beyond the ten Medicare HAC, the hospital setting, and the population covered by Medicare.

Consequently, CMS adopted an approach which created a federal "floor" for the States which would require all of the States to adopt, as a minimum, the ten Medicare HACs for all hospitals, (with the exception of a special clause altering the deep vein thrombosis/pulmonary embolism condition for children and pregnant women) and the three federal National Coverage Determinations (surgery on wrong patient, wrong surgery, and wrong site surgery) for all health care providers. This minimum "floor" could be augmented by the States through the State filing a State Plan Amendment which would designate such additional "Other Provider Preventable Events" (OPPC) as the State requested and CMS approved. The OPPC can be used by a state to cover all populations, providers, and conditions which could reasonably have been prevented by the provider.

These SPAs are presently coming into CMS for approval and it is likely that many of them will involve infection control issues. Since Medicaid will now require all States to deduct payment for care made necessary by the existing Medicare HAC, those Medicare HAC which involve infection control issues will automatically also become Medicaid HCAC. These, of course are the HAC which involve CAUTI, SSI, and VCAI in the hospital setting. The OPPC mechanism will also allow the States to deny payment for outpatient infection-related OPPC and, assuming that the States follow their previous policies, some of these OPPC will affect ambulatory surgery centers, skilled nursing facilities and physician offices. By this mechanism, it is expected that this new federal regulation will encourage more rigorous infection control practices in the outpatient setting.

National Academy for State Health Policy

The National Academy for State Health Policy convened a roundtable of state and national health policy officials in October 2009 to discuss opportunities for ongoing state-federal collaborations to promote patient safety and quality improvement. In terms of reduction of HAIs, participants of the roundtable reached consensus that the use of

payment strategies demonstrated to encourage the adoption of evidence-based practices to prevent HAIs should be a priority. They agreed that in order to reduce potential undesirable consequences of payment strategies, like gamesmanship on the part of providers (e.g. present on admission coding changes), it is crucial for federal health agencies to provide technical support for actual practice transformation, and to reward high-performing states to encourage innovations. The participants also agreed that high-level roundtables, environmental scans, and ongoing, regularly scheduled meetings for promoting state-federal coordination are crucial tools and mechanisms for addressing HAIs.

Conference of State Legislatures

The National Conference of State Legislatures released a report in July 2010, providing analysis of nine state HAI public reporting laws and their implementation. These nine states included Alabama, Colorado, Delaware, Illinois, Massachusetts, New Hampshire, Oregon, Pennsylvania, and Washington. The report attributes successes in HAI reporting to federal leadership in reporting directions and methodologies, and funding from the American Recovery and Reinvestment Act, which has provided resources for training in reporting, developing prevention plans, and surveillance tools. The report also discusses the challenges to state-level HAI reporting, including states' lack of resources to build on existing federal infrastructures (e.g. NHSH), a states' lack of mechanisms to enforce mandatory reporting among physician providers, burden for hospitals to collect data on some of the HAI measures, like SSI, and electronic data system problems that hospitals have to deal with constantly, like system bugs and crashes, and challenges in setting up digital certificates.

State Departments of Health

The states of Pennsylvania, Illinois, Florida, and Missouri have been pioneers in public reporting of HAIs. Pennsylvania is the first state where hospitals are required by law to report HAI events. The state's law (Act 52 of 2007) mandates surveillance and reporting of HAIs. Hospitals are required to report HAIs occurring in all in-patient locations to the Pennsylvania Department of Health (PADOH) through NHSN, and to annually report progress in reducing the occurrences of HAIs in Pennsylvania hospitals²⁰. Since 2008, PADOH has been collecting data on HAIs, and reporting these data in real time on NHSN. HHS's efforts to reduce HAIs have been immensely strengthened by funding from the American Recovery and Reinvestment Act (2009). The state has one of the largest state-level databases of HAI events in the country, with more than 26,000 reports

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¹⁸ Buxbaum, J. (January 2010) Opportunities and Recommendations for State-FederalCoordination to Improve Health System Performance: A Focus on Patient Safety. *State Health Policy Briefing* (http://nashp.org/sites/default/files/Patient_Safety_1-12-10.pdf, accessed October 15, 2010).

¹⁹ Spences, A., Sward, D., and Ward, J. (July 2010) Lessons from the Pioneers: Reporting HAIs (http://www.ncsl.org/documents/health/haireport.pdf, assessed October 15, 2010).

⁽http://www.ncsl.org/documents/health/haireport.pdf, assessed October 15, 2010).

Pennsylvania Department of Health. (Oct 2011) 2010 Healthcare-Associated Infections (HAI) Report: Q+A (http://www.portal.state.pa.us/portal/server.pt/community/healthcare_associated_infections/14234, last accessed October 24, 2011).

submitted annually. Pennsylvania has been focusing on CAUTI and CLABSI in its public reporting of HAIs, and added surgical site infections to its efforts recently. For the SSI measure, the PADOH worked with the Statewide HAI Advisory Committee, established under Act 52, and identified six categories, including cardiac sugery, cardiac bypass grafts (single incision and dual incision), hip prosthesis, knee prosthesis, and abdominal hysterectomy. Data validation is conducted by random chart auditing to detect potential CLABSIs. Hospital comparisons are done using risk-adjusted SIRs. In 2010, 251 hospitals in Pennsylvania submitted data to NHSN continuously over a 12-month period. Between 2009 and 2010, the state saw a 3.4 percent decline in the occurrence of HAIs.

The Pennsylvania Department of Health has overcome several major challenges in its efforts to publicly report HAIs in hospital setting, one of which was to reduce reporting burden by providing technical assistance for the vast majority of the hospitals to report HAI electronically. The department examined and certified commercial EHR surveillance systems. It incentivized hospitals to report HAI data on NHSN by waiving the requirements for these facilities to report to other statewide pay-for-performance or pay-for-reporting programs. Meanwhile, the department is helping hospitals improve data quality so that the data would allow in-depth analysis of hospital performance in the prevention of HAIs. The department is also working on benchmarking hospital performance on CLABSIs.

Pennsylvania has also launched public reporting of HAIs in nursing homes. PADOH requires nursing homes to report 19 HAIs, and has developed definitions for each condition. Currently, 722 of 732 nursing homes in Pennsylvania report HAI events. Overall, more than 40,000 HAI events have been reported. The state is working with the CDC on meaningful public reporting of HAI data.

F. Private Sector Activities

Pay for Participation. Pay for participation can be a powerful incentive for provider organizations to participate in the technical assistance programs and activities that are being carried out by the AHRQ, CDC, and CMS. In order to further expand the concept of pay for participation on the part of third party payment organizations, HHS is working with State Departments of Health, State Hospital Associations, and third party payment organizations to develop guidelines and recommendations for pay for participation programs to be implemented at the state level, and that would support Action Plan goals. The guidelines would then be distributed to payer organizations across the country for consideration, adoption and implementation.

Technical assistance is a major component of the HAI prevention strategy for AHRQ, CDC, and CMS. Technical assistance often takes the form of working directly with provider organizations to implement prevention and evidence-based interventions designed to prevent and eliminate HAIs. Participation in technical assistance activities are voluntary; many organizations eagerly participate in these improvement activities,

and incentives must be developed to encourage other organizations to utilize resources and the technical assistance offered.

One of the most successful HAI intervention programs was the Michigan Keystone Project, which focused on the elimination of CLABSI using CUSP. A key component of this state-wide effort was a pay for participation incentive to Michigan hospitals provided by Blue Cross and Blue Shield of Michigan. The incentive is worth up to five percent of a hospital's inpatient and outpatient reimbursement. Half of the five percent is targeted at quality. The project starts out with a pay for participation element that has requirements such as attending meetings and conference calls as well as a minimum of 90 percent data completeness. If a hospital fails to meet these requirements, they forfeit the three percent for the program.

VI. Conclusion

CMS, working with other HHS Operating Divisions and various national and local partners, has a number of initiatives and programs to regulate and track HAIs. Compliance with these regulations and promotion of the quality based improvement practices used by CMS in concert with its partners, will improve the public's health. Increasingly, these efforts also include more direct sources of information for providers and patients, which should influence choices that help diminish and prevent HAIs.

An advantageous approach to combating the presence of HAIs would be to design an overall framework that acknowledges that infections can, and often do, traverse across all healthcare settings. This places responsibility on setting-specific roles in preventing and mitigating the trajectory of an infection. A comprehensive, system-integrating, approach would facilitate quality in patient care, and safety, as an adjoining goal of *all* interdependent units and facilities. Here *Healthcare* would take on a *systems* framework, rather than that of a singular, and insular framework.

A new framework design related to HAIs would eventually lead to a new public reporting framework, allowing the public to assess the *healthcare system* that they would prefer to seek care in, as this decision relates to the *system's* actions regarding the preventability of HAIs, achievement of better outcomes when an HAI exists, and overall systems-related services to patients. This would allow consumers to predict which facilities work collaboratively as a system to avert infections and their disease course. A shared accountability that would inevitably lead to guidelines, surveillance processes, and financial programs would be in alignment with the overall goals of a healthcare system that works collaboratively to promote health and wellness. These efforts would help achieve the ultimate goal of preventive and interventional programs comprised by all types of healthcare providers that are part of an overarching, co-consciousness regarding cross-setting culpability for infection. Additionally, this consciousness leads providers to work collaboratively and comprehensively to support infection control management, guideline development, and quality initiatives with an approach that targets how infections truly occur across settings.

National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination CHAPTER 4. OUTREACH AND MESSAGING

I. Overview

Effective communication strategies and messages to prevent and eventually eliminate HAIs (HAIs) are essential to achieving the targets and metrics associated with the Action Plan. Communicating about HAIs, however, presents special challenges, since outreach and messaging strategies must address both the universe of involved parties and such discrete audience segments as healthcare teams, academic institutions, professional groups, patients and their caregivers. Similarly, HAI messages must address multiple infections and multiple, sometimes complex, practices to prevent them.

The Action Plan's overall multi-phased approach enabled the development of strong professional partnerships that helped to identify needs and information gaps specific to a variety of audiences. Accordingly, the outreach and messaging strategy reflects considerable guidance from those professional partners as well as from subject matter experts, regional public health groups, consumer groups, other stakeholders, and members of Congress.

Messages for general and discrete audiences were developed based on communications science principles (e.g., a shared-responsibility approach, risk-communication to affected audience segments) and processes (e.g., formative environmental, audience, and media research, multilevel message-testing). In particular, environmental research revealed that to date most current national and state HAI prevention campaigns have targeted healthcare providers and institutions. In contrast, a hallmark of this plan is the national consumer campaign to empower family caregivers as partners in the HAI prevention effort.

New to the landscape of HAI communication efforts, the national consumer campaign focuses on family caregivers in hospital settings, specifically, the largest health-seeking population (older adults 65+ years) and the largest care-giving population (women 40-65 years). Together with underserved populations, these groups are critical recipients and disseminators of HAI prevention messages and reflect the U.S. Department of Health & Human Services' (HHS) efforts to engage and empower patients and other consumers as partners in preserving health and preventing disease. ²²

After the April 2011 rollout of the HHS Partnership for Patients initiative, the Outreach and Messaging Team met April 28, 2011, to align plans for our consumer campaign with objectives and planned tactics of the broader initiative. In part, because of time and

 $^{21 \ \}mathrm{Ogilvy} \ \mathrm{Public} \ \mathrm{Relations} \ \mathrm{Worldwide, environmental} \ \mathrm{scan} \ \mathrm{document} \ \mathrm{delivered} \ \mathrm{to} \ \mathrm{HHS} \ 12/08/09$

²² For similar efforts, see http://www.ahrq.gov/qual/ptcareria.htm, http://www.ahrq.gov/qual/ptcareria.htm, http://www.ahrq.gov/qual/ptcareria.htm, http://www.ahrq.gov/qual/ptcareria.htm, http://www.ahrq.gov/qual/ptcareria.htm, http://www.ahrq.gov/qual/ptcareria.htm, http://www.ahrq.gov/qual/ptcareria.htm, www.ahrq.gov/qual/ptcareria.htm, http://www.ahrq.gov/qual/ptcareria.htm, http://www.ahrq.gov/qual/ptcareria.htm, http://www.ahrq.gov/qual/ptcareria.htm, http://www.ahrq.gov/qual/ptcareria.htm, <a href="http://www.ahrq.gov/qua

budget constraints associated with the Ogilvy Worldwide contract, the group determined to narrow campaign targets to principal family caregivers and main patient groups, namely, women aged 40+ and adults aged 65+. With input from the Partnership, the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), and Centers for Medicare & Medicaid (CMS), and after focus-testing by Partnership for Patients stakeholders, HHS determined final messages to be: (1) Wash or clean hands, (2) Ask questions, (3) Vaccinate against flu and pneumonia, and (4) Ensure safe use of medical devices. To promote these messages, a trifold brochure, a 5panel wallet card, and posters were developed to be mailed to the almost 3,000 hospitals that have committed to support the goals of the Partnership for Patients. HHS will distribute additional hard copies while supplies last and electronic files for partner production. The campaign will roll out as a joint Office of the Assistant Secretary for Health (OASH)-Partnership for Patients activity, planned for November 2011. The HHS Office of Healthcare Quality (OHQ), the Office of External Affairs, and Partnership for Patients stakeholders will work with federal and nonfederal partners to disseminate the materials widely.

The dissemination of HAI prevention messages also relies on the many Operating and Staff Divisions within HHS, and, increasingly, newer partners in other federal departments, that play ongoing roles (see Section VI) in developing and communicating health messages to their numerous constituencies and the public. In addition, federal and non-federal partners are anticipated to substantially broaden the dissemination effort. Powered by traditional and new media applied across multiple audiences, messages are expected to achieve substantial, sustainable audience penetration.

II. Goals

Goal 1: Promote and sustain heightened national attention about issues surrounding HAIs among various target audiences including: healthcare providers, consumers, patients and caregivers, consumer advocacy groups, health professional organizations, media, and the public health community.

Goal 2: Develop rapid communication strategies towards preventing various types of HAIs – catheter-associated urinary tract infections (CAUTI), central line-associated bloodstream infections (CLABSI), *Clostridium difficile* infections (CDI), methicillin-resistant *Staphylococcus aureus* (MRSA), surgical site infections (SSI), and ventilator-associated pneumonia (VAP).

Goal 3: Increase knowledge and practice of key prevention strategies for the various HAIs across and within specific healthcare settings.

III. Target Audience

Table 8 gives a brief overview of the target audiences for HAI prevention as well as the key messages, tactics and associated materials or products. Some audiences are customary constituents of HHS communications and regular partners in secondary

message dissemination. Others were selected specifically to accomplish the outreach goal of maximizing the reach of our message.



Table 8. HAI Target Audiences and Key Messages, Tactics, and Materials/Products

Audience	Audience Sub- Segment	Key Messages	Communication Tactics	Materials or Products
Healthcare providers & provider organizations	-Clinicians including: -Infection Preventionists -Hospital epidemiologists -Nurses -Physicians	-Infection prevention is everyone's responsibilityWorking together, providers and patients can greatly reduce the threat of HAIsTeam up against HAIs.	-Direct outreach via HHS communication channels -Outreach through professional partners	-HHS HAI and related websites, symposia, webinars, and other products -Partner channels and products, e.g., newsletters, webinars -HAI Prevention Trainings (e.g., HHS Partnering to Heal video, CDC HAI continuing education courses, CDC HAI webinars) -CDC Guidelines http://www.cdc.gov/hicpac - Top CDC Recommendations for Preventing HAIs: http://www.cdc.gov/HAI/prevent/top-cdc-recs-prevent-hai.html - CDC Prevention Toolkits http://www.cdc.gov/HAI/prevent/prevention-tools.html - CDC HAI resources: http://www.cdc.gov/handhygiene a. AHRQ Morbidity and Mortality Rounds http://www.cdc.gov/handhygiene a. AHRQ Patient Safety Organizations http://www.pso.ahrq.gov/ c. Guidance of Public Reporting of HAIs http://www.cdc.gov/hicpac/pubReportGuide/publicReportingHAI.html d. National Healthcare Safety Network http://www.cdc.gov/nhsn/
Healthcare industry	-Hospital CEOs -Hospital administrators -Hospital boards	-HAIs occur in all kinds of settings, including, hospitals, surgical centers, hemodialysis centers, community clinics, and othersHAIs impose a substantial economic burden on the healthcare systemEncourage accountability, transparency, and patient partnershipsTeam up against HAIs.	-Engage senior leadership through regular timely information about public reporting, prevention practices, potential savings in dollars and lives.	- CDC HAI resources: http://www.cdc.gov/hai - CDC Prevention Toolkits http://www.cdc.gov/HAI/prevent/prevention_tools.ht ml - Top CDC Recommendations for Preventing HAIs: http://www.cdc.gov/HAI/prevent/top-cdc-recs- prevent-hai.html -CDC Guidelines http://www.cdc.gov/hicpac CDC's HAI Tracking System, the National Healthcare Safety Network: http://www.cdc.gov/nhsn

Section 3. Acute Care I				CDC's HAI as a Winnable Battle: http://www.cdc.gov/WinnableBattles/HealthcareAssociatedInfections/index.html
Healthcare Personnel (including acute care hospitals, ambulatory surgical centers, and end-stage renal disease facilities)	-Administrative -Food Service -Environmental Services -All others who work or volunteer in a healthcare setting	-Infection prevention is everyone's responsibilityWorking together, the threat of HAIs can be greatly reducedTeam up against HAIs.		- CDC HAI resources: http://www.cdc.gov/hai - CDC Dialysis resources: http://www.cdc.gov/dialysis CDC Guidance for Outpatient Settings: http://www.cdc.gov/HAI/settings/outpatient/outpatient-settings.html CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities 2008 http://www.cdc.gov/hicpac/Disinfection Sterilization/toc.html CDC Sharps Safety resources: http://www.cdc.gov/sharpssafety CDC Injection Safety resources: http://www.cdc.gov/injectionsafety CDC Hand Hygiene resources: http://www.cdc.gov/handhygiene
Under-represented communities	-Spanish-language audiences -Native Americans -Low-literacy audience -Minority populations -Elderly	-Infection prevention is everyone's responsibilityAs a patient, it is vital to your health to guard against HAIsWorking together, the threat of HAIs can be greatly reducedDo the WAVE: Wash hands, Ask questions, Vaccinate against flu and pneumonia, and Ensure safe use of medical devices.	-Incorporate HAI messages in ongoing minority outreach activities	- AHRQs "Questions are the Answer Campaign" Main Page: http://www.ahrq.gov/questions/ Tips and Tools: http://www.ahrq.gov/questions/tipstools.htm Spanish-language Main Page: http://www.ahrq.gov/preguntas/ Twenty Tips to Prevent Medical Errors: http://www.ahrq.gov/consumer/20tips.htm - CDC HAI resources: http://www.cdc.gov/hai and patient safety resources: http://www.cdc.gov/HAI/patientSafety/patient-safety.html - CDC Hand Hygiene materials: http://www.cdc.gov/handhygiene/Patient materials.h tml

Section 5. Acute Care Flosp			- SHEA/IDSA/CDC Compendium of Patient Guides: http://www.shea-online.org/about/patientguides.cfm
Women ages 40 to 65/Family caregivers	-Infection prevention is everyone's responsibilityTeam up against HAIsWorking together, the threat of HAIs can be greatly reducedAs a patient or caregiver, it is vital to your own and others' health to guard against HAIsDo the WAVE: Wash hands, Ask questions, Vaccinate against flu and pneumonia, and Ensure safe use of medical devices.	-Consumer outreach campaign	AHRQs "Questions are the Answer Campaign" Main Page: http://www.ahrq.gov/questions/ Tips and Tools: http://www.ahrq.gov/questions/tipstools.htm Spanish-language Main Page: http://www.ahrq.gov/preguntas/ Twenty Tips to Prevent Medical Errors: http://www.ahrq.gov/consumer/20tips.htm - CDC HAI resources: http://www.cdc.gov/hai and patient safety resources: http://www.cdc.gov/HAI/patientSafety/patient-safety.html - CDC Hand Hygiene materials: http://www.cdc.gov/handhygiene/Patient materials.html - SHEA/IDSA/CDC Compendium of Patient Guides: http://www.shea-online.org/about/patientguides.cfm
Older adults ages 65+ or use "patients"(campaign will target)	-Infection prevention is everyone's responsibilityTeam up against HAIsWorking together, the threat of HAIs can be greatly reducedAs a patient or caregiver, it is vital to your own and others' health to guard against HAIsDo the WAVE: Wash hands, Ask questions, Vaccinate against flu and pneumonia, and Ensure safe use of medical devices.	-Consumer outreach campaign	- AHRQs "Questions are the Answer Campaign" Main Page: http://www.ahrq.gov/questions/ Tips and Tools: http://www.ahrq.gov/questions/tipstools.htm Spanish-language Main Page: http://www.ahrq.gov/preguntas/ Twenty Tips to Prevent Medical Errors: http://www.ahrq.gov/consumer/20tips.htm - CDC HAI resources: http://www.cdc.gov/hai and patient safety resources: http://www.cdc.gov/HAI/patientSafety/patient-safety.html - CDC Hand Hygiene materials: http://www.cdc.gov/handhygiene/Patient materials.html - SHEA/IDSA/CDC Compendium of Patient Guides: http://www.shea-online.org/about/patientguides.cfm

Section 3: Acute Care Hospitals					
Medicare quality	-Clinicians	Key messages from campaign that	-Outreach to facilities	-Clinically focused tools designed by AHRQ, CDC,	
improvement	-Nursing and	Medicare QI contractors can amplify	and providers who	National Kidney Foundation (for dialysis), and other	
contractors (e.g.,	ancillary care staff in	with their targets:	have already agreed to	patient safety organizations.	
Quality Improvement	acute-care hospitals	-HAIs occur in all kinds of settings,	work with Medicare	HHS HAI and related websites, symposia,	
Organizations	and dialysis facilities	including, hospitals, surgical centers,	QI contractors on	webinars, and other products	
[QIOs], ESRD	-Hospital "C-suite"	hemodialysis centers, community	quality improvement	-Partner channels and products, e.g., newsletters,	
Network	executives	clinics, and others.	(especially patient	webinars	
Organizations)	-Dialysis facility	-HAIs impose a substantial economic	safety) goals.	-HAI Prevention Training, computer-based	
	administrators and	burden on the healthcare system.	-Outreach to local and		
	medical directors (at	-Encourage accountability,	regional partners who		
	local and "chain"	transparency, and patient partnerships.	share commitment to		
	levels)	-Team up against HAIs.	patient safety (e.g.,		
	-State- and locally	**Messages specific to Medicare QI	state departments of		
	based hospital or	contractors (to facilities and providers	health, patient		
	nephrology care	already recruited for QI partnership):	advocates, state		
	associations	- There is always room to improve	provider associations).		
	-Inpatient and	performance, especially when patient	- Success stories that		
	outpatient dialysis	safety is at stake.	demonstrate how		
	facilities	- Don't give up—your Medicare QI	other partner facilities		
		partner can help support your	and providers have		
		continued and sustained improvement	worked to make care		
		with reliable, effective tools that	safer.		
		supplement what you have already	-Other QI tools to		
		been doing to keep your patients safe.	promote innovation		
		-Medicare QI partners are available to	spread (e.g.,		
		support your continued improvement,	convening learning		
		and to transfer the skills and	networks and		
		knowledge your staff needs to sustain	collaboratives).		
		gains in improving patient safety.			
		-Gaining buy-in from your leadership			
		team will help spread and sustain your			
		efforts to keep patients safe.			

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Section 3: Acute Care Hospitals

Public health agencies and organizations at the local, state, regional and federal level	-State health officers -State epidemiologists -State HAI coordinators -Public information officers	-Role of state and local health departments in HAI prevention - State and local health departments sit at the nexus of healthcare and the communityState and local health departments play a key role in promoting prevention of HAIs and helping fill gaps in patient protections for ambulatory and long term care settings.	-Conference calls -Webinars -Release of key messages -Outreach to partner organizations (e.g., CSTE, ASTHO, NAACHO, NPHIC)	- CDC state-based prevention activities: http://www.cdc.gov/HAI/stateplans/HAIstatePlans- map.html -CDC state resources: http://www.cdc.gov/hai/recoveryact -CDC Guidelines http://www.cdc.gov/hicpac - Top CDC Recommendations for Preventing HAIs: http://www.cdc.gov/HAI/prevent/top-cdc-recs- prevent-hai.html - CDC Prevention Toolkits http://www.cdc.gov/HAI/prevent/prevention tools.ht
Academia (Schools of Medicine, Nursing, Pharmacy, Public Health, et al)	Health Professional Students, Educators	-Teamwork, effective communication and personal accountability help to create a hospital culture of patient safety		HAI Prevention Training, Partnering to Heal, available at http://www.hhs.gov/partneringtoheal -CDC Guidelines http://www.cdc.gov/hicpac - Top CDC Recommendations for Preventing HAIs: http://www.cdc.gov/HAI/prevent/top-cdc-recs- prevent-hai.html - CDC Prevention Toolkits http://www.cdc.gov/HAI/prevent/prevention_tools.ht ml - CDC HAI resources: http://www.cdc.gov/hai

Key

AHRQ: Agency for Healthcare Research and Quality

ASTHO: Association of State and Territorial Health Organizations

CDC: Centers for Disease Control and Prevention

CEOs: Chief Executive Officers

CSTE: Council of State and Territorial Epidemiologists

C-Suite: term used to collectively refer to a healthcare facility's senior executives. C-Suite gets its name because top senior executives' titles tend to start with the letter C, for *chief*, as in *chief executive officer*, *chief operating officer*, etc.

ESRD: End-Stage Renal Disease **HAI**: Healthcare-Associated Infections

HHS: U.S. Department of Health & Human Services

NACCHO: National Association of County and City Health Officials

NPHIC: National Public Health Information Coalition

PSAs: Public Service Announcement **QIOs**: Quality Improvement Organizations

QI: Quality Improvement

IV. Partnership Development

Recognizing that reducing HAIs nationally is a shared responsibility, HHS is strengthening and building new partnerships to amplify prevention messages, promote implementation of recommended practices in hospitals, ambulatory surgical centers, and end-stage renal disease facilities and monitor progress at the national, regional, and local levels. In addition, consumers should feel empowered to advocate for safe healthcare for themselves and their family members.

Principal partnerships, also depicted in Table 8, include:

- HAI professional organizations that focus on prevention
- National and state level hospital associations
- Federal, regional, state, and local public health organizations
- CMS Quality Improvement Organizations
- Academic institutions including schools of medicine, nursing, pharmacy, and public health
- Consumer advocacy organizations
- Non-profit groups interested in the prevention of HAIs

V. Evaluation

The success of the HHS outreach and messaging effort will be evaluated through a variety of process measures available through HHS and its Operating and Staff Divisions. These include:

- Outreach tools and resources:
 - o Number of media clips and estimate of impressions and types of outlets
 - Number of people downloading materials from HHS campaign site, i.e., resources at www.healthcare.gov, ASH/HAI, and OHO sites
 - Web traffic on HHS campaign site and Agency/Offices HAI websites
 - Number of educational materials distributed (e.g., hard-copy)
 - o Number of people on HHS, Agencies/Offices HAI listservs
 - Number of people who have signed up to be on HHS, Agencies/Offices HAI listservs
 - Number of states who distribute the information to facilities
 - o Number of partners who distribute educational materials to membership
 - Number of requests for information and educational resources
- Analysis of social media metrics:
 - o Traffic on blogs
 - o Comments on blogs
 - o Twitter impressions
 - Facebook impressions
 - Number of sites that syndicate content information

- Number of partner sites that post links back to HHS HAI campaign site or Agencies/Offices HAI sites
- Educational activities:
 - Number of educational activities conducted each year (e.g., continuing education courses, webinars, and trainings)
 - Number of healthcare providers educated at each educational activity (e.g., continuing education courses, webinars and trainings)
 - o Number of partners who distribute educational activities
 - Number of groups that are working with the 2009 American Recovery and Reinvestment Act-funded HAI State Plan Collaboratives

VI. Activities of Participating HHS Operating and Staff Divisions and Other Federal Agencies²³

Each Federal agency participating in the outreach and messaging component of the Action Plan campaign plays an important role in communicating appropriate and relevant messages to their constituencies. Listed below are examples of specific HAI-related communications activities organized by each Operating or Staff Division:

Office of the Secretary/Office of the Assistant Secretary for Health

- Coordinates a consumer media campaign for the prevention of HAIs
- Solicits public comment on the *Action Plan* and develops strategic partnerships for implementation of the plan
- Develops and communicates training resources to support the elimination of HAIs and promote a culture of safety
- Works to establish and disseminates objectives and targets for Healthy People 2020 in its new HAI topic area

Agency for Healthcare Research and Quality

- Promotes and implements research findings and programs focused on preventing HAIs with a goal of improving the quality, safety, efficiency, and effectiveness of healthcare. Such programs include:
 - The national implementation and expansion of the Comprehensive Unit-based Safety Program, an initiative proven to reduce HAIs by improving patient care culture in a healthcare setting by integrating communication, teamwork, and leadership
 - A system to voluntarily collect patient safety data through Patient Safety
 Organizations and share the data via the Network of Patient Safety Databases.
- Develops market research strategies to better communicate the Agency's research agenda on reducing various HAIs: CAUTI, CLABSI, CDI, MRSA, SSI and VAP. This work is done in various settings including hospitals, ambulatory settings, end-stage renal disease facilities and nursing homes

²³ For a listing of web-based Federal Resources, please see http://www.hhs.gov/ash/initiatives/hai/resources/index.html.

- Designs and markets materials from evidence-based tools and resources for healthcare providers and consumers
- Disseminates HAI research results to key stakeholders and develops partnerships using various communications media, including electronic and print newsletters, podcasts, public awareness campaigns, press releases, and social media
- Tracks the impact of AHRQ's research and resources to capture and report changes in clinical practice, policy, and patient outcomes through multiple communications venues
- Collects metrics to highlight the results and effectiveness of AHRQ's communication and dissemination activities
- Publicizes the Agency's funding activities that support research for reducing and preventing HAIs to the public and the research community
- Supports the goals of the Partnership for Patients, including communications and outreach approaches

Centers for Disease Control and Prevention

CDC, through the Division of Healthcare Quality Promotion, develops and implements communications outreach and messages that emphasize the importance of prevention to eliminate HAIs. CDC's role related to outreach and messaging on the topic of HAIs includes:

- Campaigns and Educational Materials
 - Develops and conducts national campaigns aimed at healthcare providers and patients/public to prevent HAIs
 - Conducts formative research to guide the development of educational materials and campaigns; conducts qualitative/quantitative evaluations to assess the impact of educational materials and campaigns, including
 - Get Smart for Healthcare²⁴ (promoting antimicrobial stewardship among clinicians, formerly the 12 Step Campaign to Prevent Antimicrobial Resistance);
 - One and Only Campaign²⁵ (promoting safe injection practices among patients and providers in outpatient settings);
 - National MRSA Education Initiative²⁶ (promoting awareness of MRSA skin and soft tissue infections among the public/"moms");
 - Preventing Infections in Cancer Patients (educates patients and family caregivers about personal infection prevention and provides resources to ensure safe care in outpatient oncology clinics); and,
 - Hand Hygiene Saves Lives²⁷ (patient empowerment video, brochures, and posters promoting hand hygiene).
- Media and Electronic Outlets (i.e., press, web, smart phone applications, etc.) including:
 - Responds to press inquiries from national, regional and local media outlets on a variety of HAI topics

²⁴ http://www.cdc.gov/getsmart/healthcare/

²⁵ http://www.oneandonlycampaign.org/

²⁶ http://www.cdc.gov/mrsa/mrsa_initiative/skin_infection/index.html

²⁷ http://www.cdc.gov/handhygiene/

- o Works with top-tier media outlets to secure HAI related articles
- o Develops and maintains topic pages on HAIs, guidelines, FAQ sheets, etc.
- Coordinates the <u>CDC Safe Healthcare blog</u>²⁸ which encourages clinicians and consumers to discuss topics about making healthcare safer by preventing infections in healthcare settings
- Maintains several HAI web sites, including http://www.cdc.gov/hai, which provides links to CDC resources, including estimates of HAIs, lists of infectious diseases in healthcare settings, and information on antimicrobial resistance
- Conducts outreach to clinicians through on-line partners. For example, CDC has joined forces with Medscape to present the <u>CDC Expert Commentary</u> <u>Series</u>²⁹, which is designed to deliver CDC's guidance to Medscape's physicians, nurses, pharmacists, and other healthcare professionals.

Centers for Medicare & Medicaid Services

- Leverages and communicates with relevant groups about payment policies to enhance delivery of quality care. Among these are:
 - Value-based purchasing frameworks that tie accomplishment on quality measures to reimbursement rates for hospital and end-stage renal disease services in the Medicare program
 - Present on Admission Indicator Reporting Policy, which tracks whether certain conditions or patient states have been acquired during an inpatient hospital stay or whether they were community acquired
 - Hospital-Acquired Conditions payment policy, which may prevent hospitals from receiving additional Medicare payment for cases in which one of the conditions involved in the inpatient visit was not present when the patient was admitted to the hospital (e.g., complications arising from the infection of the surgical site after coronary artery bypass graft surgery)
 - Incentives (additional program payments) for hospitals and other types of Medicare- or Medicaid-participating providers to report data on clinical quality measures (e.g., Electronic Health Records Incentive Program for Medicare or Medicaid, Hospital Inpatient Quality Reporting Program)
- Uses cadre of Medicare- and Medicaid-focused quality improvement contractors to communicate with and activate providers and facilities on evidence-based strategies for continuing and sustaining improvement on patient safety/infection control processes. Examples include:
 - The nation's 53 Quality Improvement Organizations (QIOs), which deliver services locally through a national network of 53 independent organizations located in each of the 50 states, the District of Columbia, Puerto Rico and the Virgin Islands. QIOs engage providers and practitioners in focused quality improvement initiatives as part of CMS' commitment to ensuring consistent, high-quality healthcare for Medicare beneficiaries across the country

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²⁸ http://blogs.cdc.gov/safehealthcare

http://www.medscape.com/partners/cdc/public/cdc-commentary

- The nation's 18 End-stage Renal Disease Networks (ESRD NWs), which oversee the quality of care patients with end-stage renal disease receive and provide technical assistance to these patients and their care providers
- External Quality Review Organizations, which perform independent reviews of managed care organizations that provide services for Medicaid beneficiaries at the state level
- Publicly reports quality data through suite of Compare websites, including Hospital Compare and Dialysis Facility Compare
- Makes and communicates national coverage decisions that incorporate best available evidence on medical technologies that improve patient outcomes
- Sets and communicates minimum health and safety standards that providers and suppliers must meet in order to become Medicare and Medicaid certified, which serve as the foundation for improving quality and protecting the health and safety of beneficiaries (i.e., Conditions of Participation, Conditions for Coverage). These standards are enforced through state survey agencies and other accreditation bodies (e.g., The Joint Commission). CMS conducts ongoing outreach and training to facilities and the survey enforcement bodies about these health and safety standards. (For instance, hospitals are held to specific infection control standards whereby hospitals must prevent, control, and investigate infections and communicable diseases.)

Food and Drug Administration

- Publicly communicates information about antimicrobial drugs, vaccines, diagnostics, and personal protective equipment intended to prevent, reduce or treat infections
- Publicly communicates safety information about catheters, ventilators, and other hospital-related medical equipment that might be associated with HAIs; Provides guidance about product-specific safety-related issues to manufacturers and healthcare professionals, when needed

Health Resources and Services Administration

• Provides resources to train health professionals and address workforce issues

Indian Health Service

- Through multiple venues, provides Native American tribes and communities (patients, staff, and practitioners) with infection control and prevention information
- Supports partnerships, involvement, and collaboration among patients, departments, staff, and others within and outside of the Agency to prevent and control HAIs

National Institutes of Health

 Supports and conducts biomedical research and research training and disseminates information to public and professional audiences. One area of

- investigation is the pathogenesis of multidrug resistant organisms and other pathogens of importance in the healthcare setting
- National Institutes of Health (NIH) Clinical Center's Hospital Epidemiology Service directs hospital-associated infection prevention efforts through a collaborative, coordinated, and continuous process of surveillance, education, and communication founded on current scientific knowledge and consistent with regulatory requirements
- Intramural investigators who represent NIH in professional societies and on guideline committees directly communicate scientific information used to establish national policies and recommendations for prevention and management of HAIs
- Employs multimedia forms of training and guidelines on infection prevention for healthcare workers at the Clinical Center. The Clinical Center provides patient information on infection control in both English and Spanish.
- Conducts presentations to healthcare groups on epidemiology matters
- Provides information on infection control to the NIH Clinical Center staff and
 patients and to the public through the NIH Health Information Pages³⁰, and
 Medline Plus, a web-based consumer health information service operated by the
 National Library of Medicine

U.S. Department of Veterans Affairs

- Facilitates efforts for infection control and prevention through numerous communications mechanisms and across multiple medical care programs whereby infection control and prevention becomes "everyone's responsibility"
- Uses the Inpatient Evaluation Center to conduct nationwide surveillance of healthcare-associated conditions and communicates findings to multiple audiences
- At each Veterans Affairs facility, directly communicates prevention practices to reduce and prevent the spread of antibiotic resistant organisms, such as MRSA

VII. Conclusion

Effective, timely and targeted communication strategies and messages to prevent and eliminate HAIs are essential to achieving the targets and metrics associated with the Action Plan.

Messages, based on target audience research, heavily rely on themes of partnerships among patients, their families, and healthcare providers for the prevention of HAIs. A national media campaign targeting consumers will engage family caregivers as partners in the HAI prevention effort.

As the HAI prevention effort grows, the Outreach and Messaging Working Group continues to formulate and conduct strategic communications activities, disseminate key

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³⁰ Can be found at http://health.nih.gov/category/Infections

messages to target audiences, and promote the overall efforts of the HHS Steering Committee for the Prevention of HAIs.

